IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

IN RE LIPITOR ANTITRUST LITIGATION	MDL No. 2332
THIS DOCUMENT RELATES TO: ALL END-PAYOR CLASS ACTIONS	Master Docket No.: 3:12-cv-2389 (PGS/DEA)

END-PAYOR PLAINTIFFS' CONSOLIDATED CLASS ACTION COMPLAINT AND JURY DEMAND

TABLE OF CONTENTS

I. INTRODUCTION

1. This case involves the Defendants' anticompetitive scheme to delay the market entry of generic Lipitor, a statin used to lower cholesterol.

2. Warner-Lambert[1] secured a patent for Lipitor in 1987. With subsequent extensions, this patent gave Warner-Lambert over thirteen years of market exclusivity for Lipitor, which it launched in 1997.

3. Typically, the expiration of such a patent would allow for generic drug sales—at prices far below those of the branded drug—to commence. But Warner-Lambert was greedy and was not satisfied with the statutory norm. Seeking to maintain the supracompetitive profits derived from the exclusive sale of Lipitor, the Pfizer defendants[2] ("Pfizer") initiated an unlawful anticompetitive scheme to extend their market exclusivity by delaying the market entry of generic Lipitor.

4. In short, the Defendants' scheme included, among other things, the following anticompetitive acts:

- Fraudulently obtaining a second, duplicative patent from the United States Patent and Trademark Office ("PTO") and then wrongfully listing that patent in the book of Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book"), published by the United States Food and Drug Administration ("FDA");
- Engaging in serial sham litigation in connection with the fraudulently-obtained patent in order to delay market entry of generic Lipitor;
- Filing a sham citizen petition with the FDA in an effort to stall approval of generic Lipitor;
- Entering an anticompetitive and unlawful reverse payment "pay-for-delay" market allocation agreement, which extended beyond the exclusionary reach of the relevant patents, whereby Pfizer provided substantial payments and other valuable consideration

[1] Pfizer acquired Warner-Lambert and its patents in 2000.

[2] Pfizer Inc., Pfizer Ireland Pharmaceuticals, Warner-Lambert Company, and Warner-Lambert Company LLC.

to Ranbaxy, a generic manufacturer, in exchange for Ranbaxy's agreement to delay generic competition; and

- Thwarting any and all efforts to obtain judicial declarations that Pfizer's patents were invalid, unenforceable, and/or would not be infringed by generic Lipitor formulations, in order to avoid the triggering of Ranbaxy's anticipated 180-day first-to-file marketing exclusivity and thereby sustain Pfizer's and Ranbaxy's ability to, in concert, bottleneck other generic companies from launching generic Lipitor.

5. With this conduct, Defendants unlawfully forestalled and eliminated generic competition for Lipitor. Defendants' conduct has driven up prescription drugs costs to U.S. consumers, the state and federal governments, and third-party payors in an amount between $10 million and $19 million per day, or roughly $4 billion to $7 billion each year.

Lipitor Patents and Warner-Lambert's Fraud on the PTO

6. In 1987, the PTO granted Warner-Lambert a patent for a racemic mixture[3] that inhibited the production of cholesterol (U.S. Patent No. 4,681,893, the "Original Lipitor Patent" or the "'893 Patent"). With subsequent extensions, this patent expired on March 24, 2010.

7. Two years after receiving the Original Lipitor Patent, Warner-Lambert sought to separately patent atorvastatin, the active ingredient in Lipitor and one of the enantiomers in the racemic mixture that Warner-Lambert had already patented, in an effort to ensure an even longer period of patent-protected exclusivity for the blockbuster drug.

8. Warner-Lambert could only obtain a separate patent for atorvastatin if it had a "surprising" quality. Warner-Lambert's data clearly showed atorvastatin to be utterly ordinary, however, so Warner-Lambert decided to defraud the PTO in order to obtain the follow-on patent.

9. More specifically, in connection with this follow-on atorvastatin patent application, Warner-Lambert fraudulently claimed that the isolated enantiomer atorvastatin was, "surprisingly," ten times more active than the racemic mixture, when one skilled in the art would

[3] A racemic mixture contains an equal amount of two enantiomers; enantiomers have the same chemical formula but are arranged as mirror images.

have expected only a two-fold difference in activity. Warner Lambert knew its assertion to be false. Nevertheless, Warner-Lambert knowingly and purposefully submitted a manipulated, unscientific conglomeration of data points—cherry-picked from over a dozen separate tests performed in different formulations over several years—that falsely supported their bogus contention. Accordingly, Warner-Lambert's support for its follow-on '995 Patent lacked any basis in fact. Warner-Lambert knew that if the data were analyzed consistently with sound and reasonable scientific principles, the invention claimed in the '995 Patent would provide only a two-fold increase in activity—the same ordinary increase that was widely expected based on the prior art—and that its claimed invention would therefore not be patentable.

10. Given the duty of candor that patent applicants owe to the PTO, which requires the disclosure of all known information that may adversely affect the patentability of the claimed invention, the PTO, oblivious to Warner-Lambert's deception, relied on the corrupted data and issued the duplicative follow-on patent (U.S. Patent Number 5,273,995, the "'995 Enantiomer Patent" or the "'995 Patent" or the "follow-on patent") for the isolated enantiomer.

Efforts to Stall Approval and Delay Market Entry of Generic Lipitor

11. Driven by the massive profits that Pfizer reaped each day that Lipitor maintained its market exclusivity, and armed with the duplicative follow-on patent, which it knew was invalid and/or unenforceable, Pfizer prosecuted sham patent infringement litigation with the sole purpose of delaying market entry of generic Lipitor.

12. In particular, in early 2003, Pfizer initiated patent infringement litigation against Ranbaxy, the generic manufacturer that filed the first abbreviated new drug application ("ANDA") seeking to market generic Lipitor. The mere filing of this sham litigation triggered

an automatic statutorily-mandated thirty-month delay in the FDA's approval of Ranbaxy's ANDA.

13. On the eve of the thirty-month stay's expiration, Pfizer deployed another anticompetitive tactic to impede the FDA's approval of Ranbaxy's ANDA. On July 28, 2005, Pfizer sent a formal letter to the FDA (which it re-filed as a purported "Citizen Petition" on November 7, 2005), baselessly challenging the FDA's anticipated approval of Ranbaxy's generic Lipitor ANDA and asserting that the FDA should take into account arguments and information that lacked any regulatory, scientific, medical, or other reasonable relevance to Ranbaxy's application. The substance (or lack thereof) and timing of these submission were intended solely to further delay final FDA approval of Ranbaxy's generic Lipitor ANDA.

14. In 2008, Pfizer and Ranbaxy abandoned their adversarial positions and entered into an anticompetitive pay-for-delay settlement agreement that allowed Pfizer to prolong its Lipitor monopoly and allocated the market for the entrance of a generic bioequivalent. Pursuant to this settlement, Ranbaxy promised not to launch its generic Lipitor until November 30, 2011 and agreed not to relinquish its first-to-file 180-day marketing exclusivity for generic Lipitor, thereby effectively preventing any other generic competitor from entering the market.

15. In exchange for Ranbaxy's promise not to compete (or to allow others to compete), Pfizer made payments to Ranbaxy in the form of: (i) the forgiveness of Ranbaxy's outstanding money judgments (unrelated to the then-nonexistent marketing of generic atorvastatin calcium in the United States); and (ii) a generous market allocation agreement pursuant to which Ranbaxy was permitted to exclusively market generic Lipitor in at least eleven foreign markets. In addition to Pfizer's agreement to forgive Ranbaxy's outstanding money judgments, this market allocation settlement provided significant financial compensation to

Ranbaxy, including the significant revenues and profits obtained by Ranbaxy from marketing and selling generic Lipitor in the foreign markets.

16. To disguise its true anticompetitive purpose, the pay-for-delay settlement was entered into under cover of objectively baseless sham litigation that Pfizer brought against Ranbaxy.

17. Pfizer also purported to give Ranbaxy protection from infringement liability in connection with a variety of patents, but that "consideration" was illusory, and it was inserted into the pay-for-delay settlement merely to disguise the illegal horizontal allocation with Pfizer.

18. Pfizer also undertook a calculated pattern of sham litigation designed to delay the efforts of other generic manufacturers that sought approval to manufacture and sell generic Lipitor. This anticompetitive behavior involved, among other things, engaging in serial sham litigation concerning the fraudulently-obtained duplicative patent and thwarting any and all efforts to obtain judicial declarations that certain unasserted patents were invalid, unenforceable, and/or would not be infringed by generic Lipitor.

Defendants' Actions Delayed Generic Competition for Many Months

19. This class action complaint seeks damages on behalf of all end-payors in the United States and its territories who indirectly purchased, paid for, and/or provided reimbursement for Lipitor and/or its generic bioequivalents during the period March 24, 2010 through and until the anticompetitive effects of Defendants' conduct cease, and who were injured by Defendants' anticompetitive actions. But for Warner-Lambert's fraud, the PTO would never have issued the follow-on patent—not at any time, not in any form. And but for the fraudulently-obtained follow-on patent, sham patent infringement litigation, baseless citizen petition, and unlawful pay-for-delay market allocation agreement, a generic Lipitor equivalent

would have been available far earlier than it was. Thus, Defendants' actions prevented the class from purchasing less-expensive Lipitor, and less-expensive generic Lipitor equivalents, for at least twenty months, as it was not until November 30, 2011 that a generic bioequivalent was made available to consumers. Defendants' actions have resulted in a continuing anticompetitive harm and antitrust injury to Plaintiffs and all members of the End-Payor Class.

II. THE PARTIES

20. Plaintiff A.F.L.-A.G.C. Building Trades Welfare Plan (the "A.F.L. Plan") is a self-insured health and welfare benefit plan with its principal place of business in Mobile, Alabama. During the Class Period, as defined below, the A.F.L. Plan purchased and/or paid for some or all of the purchase price for Lipitor and/or its generic equivalent in the states of Florida, Mississippi, Virginia, Alabama, Georgia, and Kentucky. The A.F.L. Plan paid more than it would have absent Defendants' unlawful scheme to prevent and delay generic entry and was injured as a result of the illegal and wrongful conduct alleged herein.

21. Plaintiff IBEW-NECA Local 505 Health & Welfare Plan (the "IBEW Plan") is a self-insured health and welfare benefit plan with its principal place of business in Mobile, Alabama. During the Class Period, as defined below, the IBEW Plan purchased and/or paid for some or all of the purchase price for Lipitor and/or its generic equivalent in the states of Alabama and Louisiana. The IBEW Plan paid more than it would have absent Defendants' unlawful scheme to prevent and delay generic entry and was injured as a result of the illegal and wrongful conduct alleged herein.

22. Plaintiff MC-UA Local 119 Health and Welfare Plan (the "UA Plan") is a self-insured health and welfare benefit plan with its principal place of business in Mobile, Alabama. During the Class Period, as defined below, the UA Plan purchased and/or paid for some or all of the purchase price for Lipitor and/or its generic equivalent in the states of Mississippi, Alabama,

and Texas. The UA Plan paid more than it would have absent Defendants' unlawful scheme to prevent and delay generic entry and was injured as a result of the illegal and wrongful conduct alleged herein.

23. Plaintiff New Mexico United Food and Commercial Workers Union's and Employers' Health and Welfare Trust Fund ("NMUFCW") is a Taft-Hartley fund with its principal place of business in Albuquerque, New Mexico. During the Class Period, as defined below, NMUFCW purchased and/or paid for some or all of the purchase price for Lipitor and/or its generic equivalent in the state of New Mexico. NMUFCW paid more than it would have absent Defendants' unlawful scheme to prevent and delay generic entry and was injured as a result of the illegal and wrongful conduct alleged herein.

24. Plaintiff Louisiana Health Service Indemnity Company d/b/a Bluecross/Blueshield of Louisiana ("BCBSLA") is a domestic health insurance corporation licensed to conduct business in the State of Louisiana. BCBSLA is involved in the business of providing health benefits, among others, to covered lives. During the Class Period, as defined below, BCBSLA purchased and/or paid for some or all of the purchase price for Lipitor and/or its generic equivalent in the states of Missouri, Pennsylvania, Illinois, Rhode Island, Louisiana, Texas, Ohio, Kansas, Alabama, Virginia, Minnesota, Massachusetts, Tennessee, Florida, Arizona, Mississippi, New Jersey, California, New York, Oklahoma, Michigan, Georgia, Utah, Washington, Maine, Arkansas, North Carolina, and Nevada. BCBSLA paid more than it would have absent Defendants' unlawful scheme to prevent and delay generic entry and was injured as a result of the illegal and wrongful conduct alleged herein.

25. Plaintiff Bakers Local 433 Health Fund ("BLF") is a jointly administered Taft-Hartley fund authorized pursuant to Section 302(c)(5) of the National Labor Relations Act, with

its principal place of business in North Sioux City, South Dakota, and an employee welfare benefit plan as defined in Section 3(1) of the Employee Retirement Income Security Act of 1974 ("ERISA"). BLF provides health benefits, including prescription drug benefits, to its approximately 400 active participants, plus their spouses and dependents. During the Class Period, as defined below, BLF purchased and/or paid for some or all of the purchase price for Lipitor and/or its generic equivalent in the states of Iowa, Nebraska, and South Dakota. BLF paid more than it would have absent Defendants' unlawful scheme to prevent and delay generic entry and was injured as a result of the illegal and wrongful conduct alleged herein.

26. Plaintiff Minneapolis Auto Dealers Employee Benefit Fund ("MADF") is a jointly administered Taft-Hartley fund authorized pursuant to Section 302(c)(5) of the National Labor Relations Act, with its principal place of business in Minneapolis, Minnesota, and an employee welfare benefit plan as defined in Section 3(1) of ERISA. MADF provides health benefits, including prescription drug benefits, to its approximately 400 active participants, plus their spouses and dependents. During the Class Period, as defined below, MADF purchased and/or paid for some or all of the purchase price for Lipitor and/or its generic equivalent in the states of Ohio and Minnesota. MADF paid more than it would have absent Defendants' unlawful scheme to prevent and delay generic entry and was injured as a result of the illegal and wrongful conduct alleged herein.

27. Plaintiff Graphic Communications Local 1B Health and Welfare Fund "A" ("GCLF") is a jointly administered Taft-Hartley fund authorized pursuant to Section 302(c)(5) of the National Labor Relations Act, with its principal place of business in St. Paul, Minnesota, and an employee welfare benefit plan as defined in Section 3(1) of ERISA. GCLF provides health benefits, including prescription drug benefits, to its approximately 400 active participants, plus

their spouses and dependents. During the Class Period, as defined below, GCLF purchased and/or paid for some or all of the purchase price for Lipitor and/or its generic equivalent in the states of Minnesota, Illinois, Alabama, and Texas. GCLF paid more than it would have absent Defendants' unlawful scheme to prevent and delay generic entry and was injured as a result of the illegal and wrongful conduct alleged herein.

28. Plaintiff Twin Cities Bakery Workers Health and Welfare Fund ("TCBWF") is a jointly administered Taft-Hartley fund authorized pursuant to Section 302(c)(5) of the National Labor Relations Act, with its principal place of business in Eagan, Minnesota, and an employee welfare benefit plan as defined in Section 3(1) of ERISA. TCBWF provides health benefits, including prescription drug benefits, to its approximately 1,200 active participants, plus their spouses and dependents. During the Class Period, as defined below, TCBWF purchased and/or paid for some or all of the purchase price for Lipitor and/or its generic equivalent in the states of Minnesota, Pennsylvania, and Illinois. TCBWF paid more than it would have absent Defendants' unlawful scheme to prevent and delay generic entry and was injured as a result of the illegal and wrongful conduct alleged herein.

29. Plaintiff Bricklayers and Masons' Local Union No. 5, Ohio Health & Welfare Fund ("Bricklayers") is a health and welfare fund, located at 6200 Rockside Woods Blvd. N., Suite 210, Independence, Ohio 44131. During the Class Period, as defined below, Bricklayers purchased and/or paid for some or all of the purchase price for Lipitor and/or its generic equivalent in the states of Nebraska and West Virginia. Bricklayers paid more than it would have absent Defendants' unlawful scheme to prevent and delay generic entry and was injured as a result of the illegal and wrongful conduct alleged herein.

30. Plaintiff Florida Laborers Health and Welfare Fund ("Florida Laborers") is a trust fund administered pursuant to the requirements of the Taft-Hartley Act, 29 U.S.C. § 186, by trustees appointed in equal numbers by labor representatives and union representatives. Florida Laborers is an "employee welfare benefit plan" and "employee benefit plan" maintained pursuant to Section 302(c)(5) of the Labor Management Relations Act ("LMRA"), 29 U.S.C. § 186(c)(5), and as defined by Sections 1002(1) and (3) of ERISA, 29 U.S.C. § 1001, *et. seq*. As such, Florida Laborers is a legal entity entitled to bring suit in its own name pursuant to 29 U.S.C. § 1132(d). Florida Laborers' place of administration is located in Goodlettsville, Tennessee. During the Class Period, as defined below, Florida Laborers purchased and/or paid for some or all of the purchase price for Lipitor and/or its generic equivalent in the states of Florida, Pennsylvania, and Illinois. Florida Laborers paid more than it would have absent Defendants' unlawful scheme to prevent and delay generic entry and was injured as a result of the illegal and wrongful conduct alleged herein.

31. Plaintiff Southeast Laborers Health and Welfare Fund ("Southeast Laborers") is a trust fund administered pursuant to the requirements of the Taft-Hartley Act, 29 U.S.C. § 186, by trustees appointed in equal numbers by labor representatives and union representatives. Southeast Laborers is an "employee welfare benefit plan" and "employee benefit plan" maintained pursuant to Section 302(c)(5) of the LMRA, 29 U.S.C. § 186(c)(5), and as defined by Sections 1002(1) and (3) of ERISA, 29 U.S.C. § 1001, *et. seq*. As such, Southeast Laborers is a legal entity entitled to bring suit in its own name pursuant to 29 U.S.C. § 1132(d). Southeast Laborers' place of administration is located in Goodlettsville, Tennessee. During the Class Period, as defined below, Southeast Laborers purchased and/or paid for some or all of the purchase price for Lipitor and/or its generic equivalent in the states of Georgia, Tennessee, South

Carolina, Alabama, and Pennsylvania. Southeast Laborers paid more than it would have absent Defendants' unlawful scheme to prevent and delay generic entry and was injured as a result of the illegal and wrongful conduct alleged herein.

32. Plaintiff Fraternal Order of Police, Fort Lauderdale Lodge 31, Insurance Trust Fund (the "FOP Trust") is a governmental health insurance plan established pursuant to Florida law and resolution of the Fort Lauderdale City Commission. The FOP Trust is managed by a Board of Trustees and provides health and major medical insurance, including prescription drugs, to active and retired Ft. Lauderdale City police officers and their dependants. During the Class Period, as defined below, the FOP Trust purchased and/or paid for some or all of the purchase price for Lipitor and/or its generic equivalent in the states of New Jersey, Florida, Pennsylvania, Nevada, Georgia, and North Carolina. The FOP Trust paid more than it would have absent Defendants' unlawful scheme to prevent and delay generic entry and was injured as a result of the illegal and wrongful conduct alleged herein.

33. Plaintiff International Brotherhood of Electrical Workers Local 98 ("IBEW Local 98") is an "employee welfare benefit plan" and "employee benefit plan" maintained pursuant to Section 302(c)(5) of the LMRA, 29 U.S.C. § 186(c)(5), and as defined by Sections 1002(1) and (3) of ERISA, 29 U.S.C. § 1001, *et seq*. As such, IBEW Local 98 is a legal entity entitled to bring suit in its name pursuant to Section 1132(d). IBEW Local 98's office, from which it pays medical benefits, including benefits for prescription drugs, is located in Philadelphia, Pennsylvania. Pursuant to the Trust Agreement under which it was created, IBEW Local 98 provides comprehensive health care benefits to approximately 3,000 participants who are employed under various collective bargaining agreements, and their dependents, as well as retirees. During the Class Period, as defined below, IBEW Local 98 purchased and/or paid for

some or all of the purchase price for Lipitor and/or its generic equivalent in the states of New Jersey, Pennsylvania, Ohio, Virginia, Delaware, Florida, New Mexico, Maryland, Georgia, and Arizona. IBEW Local 98 paid more than it would have absent Defendants' unlawful scheme to prevent and delay generic entry and was injured as a result of the illegal and wrongful conduct alleged herein.

34. Plaintiff Local 17 Hospitality Benefit Fund ("LHBF") is a jointly administered Taft-Hartley fund authorized pursuant to Section 302(c)(5) of the National Labor Relations Act, with its principal place of business in Bloomington, Minnesota, and an employee welfare benefit plan as defined in Section 3(1) of ERISA. LHBF provides health benefits, including prescription drug benefits, to its active participants, plus their spouses and dependents. During the Class Period, as defined below, LHBF purchased and/or paid for some or all of the purchase price for Lipitor and/or its generic equivalent in the state of Minnesota. LHBF paid more than it would have absent Defendants' unlawful scheme to prevent and delay generic entry and was injured as a result of the illegal and wrongful conduct alleged herein.

35. Plaintiff New York Hotel Trades Council & Hotel Association of New York City, Inc. Health Benefits Fund ("NYHTC") is a jointly-trusteed employee benefits fund which operates for the benefit of active and retired unionized hotel workers in the New York metro area. NYHTC has its principal place of business at 305 West 44th Street, New York, New York, 10036 and, thus, is a citizen of New York. During the Class Period, as defined below, NYHTC purchased and/or paid for some or all of the purchase price for Lipitor and/or its generic equivalent in the state of New York. NYHTC paid more than it would have absent Defendants' unlawful scheme to prevent and delay generic entry and was injured as a result of the illegal and wrongful conduct alleged herein.

36. Plaintiff Greater Metropolitan Hotel Employers-Employees Health and Welfare Fund ("GMHEF") is a jointly administered Taft-Hartley fund authorized pursuant to Section 302(c)(5) of the National Labor Relations Act, with its principal place of business in Bloomington, Minnesota, and an employee welfare benefit plan as defined in Section 3(1) of ERISA. GMHEF provides health benefits, including prescription drug benefits, to its active participants, plus their spouses and dependents. During the Class Period, as defined below, GMHEF purchased and/or paid for some or all of the purchase price for Lipitor and/or its generic equivalent in the state of Minnesota. GMHEF paid more than it would have absent Defendants' unlawful scheme to prevent and delay generic entry and was injured as a result of the illegal and wrongful conduct alleged herein.

37. Plaintiff Laborers' International Union of North America Local 17 Health and Benefit Fund is a health and welfare benefit fund with its principal place of business located in Newburgh, New York, and is involved in the business of providing health and pension benefits, among others, to covered lives. During the Class Period, as defined below, Laborers' International Union of North America Local 17 purchased and/or paid for some or all of the purchase price for Lipitor and/or its generic equivalent in the states of South Carolina, New York, New Jersey, Florida, Pennsylvania, and Nevada. Laborers' International Union of North America Local 17 paid more than it would have absent Defendants' unlawful scheme to prevent and delay generic entry and was injured as a result of the illegal and wrongful conduct alleged herein.

38. Plaintiff Edward Czarnecki is a resident of Wisconsin. During the Class Period, as defined below, Mr. Czarnecki purchased and/or paid for some or all of the purchase price for Lipitor and/or its generic equivalent in the state of Wisconsin. Mr. Czarnecki paid more than he

would have absent Defendants' unlawful scheme to prevent and delay generic entry and was injured as a result of the illegal and wrongful conduct alleged herein.

39. Plaintiff Richard Holden is a resident of Florida. During the Class Period, as defined below, Mr. Holden purchased and/or paid for some or all of the purchase price for Lipitor and/or its generic equivalent in the state of Florida. Mr. Holden paid more than he would have absent Defendants' unlawful scheme to prevent and delay generic entry and was injured as a result of the illegal and wrongful conduct alleged herein.

40. Plaintiff Emilie Heinle is a resident of North Dakota. During the Class Period, as defined below, Ms. Heinle purchased and/or paid for some or all of the purchase price for Lipitor and/or its generic equivalent in the state of North Dakota. Ms. Heinle paid more than she would have absent Defendants' unlawful scheme to prevent and delay generic entry and was injured as a result of the illegal and wrongful conduct alleged herein.

41. Plaintiff Anita Cox is a resident of California. During the Class Period, as defined below, Ms. Cox purchased and/or paid for some or all of the purchase price for Lipitor and/or its generic equivalent in the states of Washington and California. Ms. Cox paid more than she would have absent Defendants' unlawful scheme to prevent and delay generic entry and was injured as a result of the illegal and wrongful conduct alleged herein.

42. Plaintiff Frank Palter is a resident of California. During the Class Period, as defined below, Mr. Palter purchased and/or paid for some or all of the purchase price for Lipitor and/or its generic equivalent in the state of California. Mr. Palter paid more than he would have absent Defendants' unlawful scheme to prevent and delay generic entry and was injured as a result of the illegal and wrongful conduct alleged herein.

43. Plaintiff Harold Blaker is a resident of Pennsylvania. During the Class Period, as defined below, Mr. Blaker purchased and/or paid for some or all of the purchase price for Lipitor and/or its generic equivalent in the state of Nevada. Mr. Blaker paid more than he would have absent Defendants' unlawful scheme to prevent and delay generic entry and was injured as a result of the illegal and wrongful conduct alleged herein.

44. Plaintiff Timothy Smith is a resident of West Virginia. During the Class Period, as defined below, Mr. Smith purchased and/or paid for some or all of the purchase price for Lipitor and/or its generic equivalent in the state of West Virginia. Mr. Smith paid more than he would have absent Defendants' unlawful scheme to prevent and delay generic entry and was injured as a result of the illegal and wrongful conduct alleged herein

45. Plaintiff Gerald Lutz is a resident of Minnesota. During the Class Period, as defined below, Mr. Lutz purchased and/or paid for some or all of the purchase price for Lipitor and/or its generic equivalent in the state of Minnesota. Mr. Lutz paid more than he would have absent Defendants' unlawful scheme to prevent and delay generic entry and was injured as a result of the illegal and wrongful conduct alleged herein.

46. Plaintiff John Gallagher is a resident of Illinois. During the Class Period, as defined below, Mr. Gallagher purchased and/or paid for some or all of the purchase price for Lipitor and/or its generic equivalent in the state of Illinois. Mr. Gallagher paid more than he would have absent Defendants' unlawful scheme to prevent and delay generic entry and was injured as a result of the illegal and wrongful conduct alleged herein.

47. Plaintiff Neil Hirsch is a resident of Illinois. During the Class Period, as defined below, Mr. Hirsch purchased and/or paid for some or all of the purchase price for Lipitor and/or its generic equivalent in the state of Illinois. Mr. Hirsch paid more than he would have absent

Defendants' unlawful scheme to prevent and delay generic entry and was injured as a result of the illegal and wrongful conduct alleged herein.

48. Plaintiff Andrew Livezey is a resident of Massachusetts. During the Class Period, as defined below, Mr. Livezey purchased and/or paid for some or all of the purchase price for Lipitor and/or its generic equivalent in the state of New Jersey. Mr. Livezey paid more than he would have absent Defendants' unlawful scheme to prevent and delay generic entry and was injured as a result of the illegal and wrongful conduct alleged herein.

49. Plaintiff Cynthia Pond is a resident of Idaho. During the Class Period, as defined below, Ms. Pond purchased and/or paid for some or all of the purchase price for Lipitor and/or its generic equivalent in the state of Idaho. Ms. Pond paid more than she would have absent Defendants' unlawful scheme to prevent and delay generic entry and was injured as a result of the illegal and wrongful conduct alleged herein.

50. Plaintiff David Pavel is a resident of Nebraska. During the Class Period, as defined below, Mr. Pavel purchased and/or paid for some or all of the purchase price for Lipitor and/or its generic equivalent in the state of Nebraska. Mr. Pavel paid more than he would have absent Defendants' unlawful scheme to prevent and delay generic entry and was injured as a result of the illegal and wrongful conduct alleged herein.

51. Plaintiff Denise McClintic is a resident of Arizona. During the Class Period, as defined below, Ms. McClintic purchased and/or paid for some or all of the purchase price for Lipitor and/or its generic equivalent in the state of Arizona. Ms. McClintic paid more than she would have absent Defendants' unlawful scheme to prevent and delay generic entry and was injured as a result of the illegal and wrongful conduct alleged herein.

52. Plaintiff Michael Saul is a resident of Texas. During the Class Period, as defined below, Mr. Saul purchased and/or paid for some or all of the purchase price for Lipitor and/or its generic equivalent in the states of Texas, Nevada, and Indiana. Mr. Saul paid more than he would have absent Defendants' unlawful scheme to prevent and delay generic entry and was injured as a result of the illegal and wrongful conduct alleged herein.

53. Plaintiff Donna Wentzel is a resident of Colorado. During the Class Period, as defined below, Ms. Wentzel purchased and/or paid for some or all of the purchase price for Lipitor and/or its generic equivalent in the state of Colorado. Ms. Wentzel paid more than she would have absent Defendants' unlawful scheme to prevent and delay generic entry and was injured as a result of the illegal and wrongful conduct alleged herein.

54. Plaintiff Edna Bell is a resident of Oklahoma. During the Class Period, as defined below, Ms. Bell purchased and/or paid for some or all of the purchase price for Lipitor and/or its generic equivalent in the state of Oklahoma. Ms. Bell paid more than she would have absent Defendants' unlawful scheme to prevent and delay generic entry and was injured as a result of the illegal and wrongful conduct alleged herein.

55. Plaintiff Edward Ellenson is a resident of Hawaii. During the Class Period, as defined below, Mr. Ellenson purchased and/or paid for some or all of the purchase price for Lipitor and/or its generic equivalent in the state of Hawaii. Mr. Ellenson paid more than he would have absent Defendants' unlawful scheme to prevent and delay generic entry and was injured as a result of the illegal and wrongful conduct alleged herein.

56. Plaintiff Jean Ellyne Dougan is a resident of Arkansas. During the Class Period, as defined below, Ms. Dougan purchased and/or paid for some or all of the purchase price for Lipitor and/or its generic equivalent in the state of Arkansas. Ms. Dougan paid more than she

would have absent Defendants' unlawful scheme to prevent and delay generic entry and was injured as a result of the illegal and wrongful conduct alleged herein.

57. Plaintiff Jeffrey P. Santarcangelo is a resident of Vermont. During the Class Period, as defined below, Mr. Santarcangelo purchased and/or paid for some or all of the purchase price for Lipitor and/or its generic equivalent in the state of Vermont. Mr. Santarcangelo paid more than he would have absent Defendants' unlawful scheme to prevent and delay generic entry and was injured as a result of the illegal and wrongful conduct alleged herein.

58. Plaintiff John Luce is a resident of South Dakota. During the Class Period, as defined below, Mr. Luce purchased and/or paid for some or all of the purchase price for Lipitor and/or its generic equivalent in the state of South Dakota. Mr. Luce paid more than he would have absent Defendants' unlawful scheme to prevent and delay generic entry and was injured as a result of the illegal and wrongful conduct alleged herein.

59. Plaintiff Joyce January is a resident of California. During the Class Period, as defined below, Ms. January purchased and/or paid for some or all of the purchase price for Lipitor and/or its generic equivalent in the state of New Mexico. Ms. January paid more than she would have absent Defendants' unlawful scheme to prevent and delay generic entry and was injured as a result of the illegal and wrongful conduct alleged herein.

60. Plaintiff Katy Miner is a resident of Iowa. During the Class Period, as defined below, Ms. Miner purchased and/or paid for some or all of the purchase price for Lipitor and/or its generic equivalent in the state of Iowa. Ms. Miner paid more than she would have absent Defendants' unlawful scheme to prevent and delay generic entry and was injured as a result of the illegal and wrongful conduct alleged herein.

61. Plaintiff Lennie Adams is a resident of Lousiana. During the Class Period, as defined below, Ms. Adams purchased and/or paid for some or all of the purchase price for Lipitor and/or its generic equivalent in the state of Louisiana. Ms. Adams paid more than she would have absent Defendants' unlawful scheme to prevent and delay generic entry and was injured as a result of the illegal and wrongful conduct alleged herein.

62. Plaintiff Nancy Billington is a resident of Montana. During the Class Period, as defined below, Ms. Billington purchased and/or paid for some or all of the purchase price for Lipitor and/or its generic equivalent in the state of Montana. Ms. Billington paid more than she would have absent Defendants' unlawful scheme to prevent and delay generic entry and was injured as a result of the illegal and wrongful conduct alleged herein.

63. Plaintiff Ray Roy is a resident of North Carolina. During the Class Period, as defined below, Mr. Roy purchased and/or paid for some or all of the purchase price for Lipitor and/or its generic equivalent in the states of North Carolina and Massachusetts. Mr. Roy paid more than he would have absent Defendants' unlawful scheme to prevent and delay generic entry and was injured as a result of the illegal and wrongful conduct alleged herein.

64. Plaintiff W. Patrick Schneese is a resident of Delaware. During the Class Period, as defined below, Mr. Schneese purchased and/or paid for some or all of the purchase price for Lipitor and/or its generic equivalent in the states of New Jersey and Delaware. Mr. Schneese paid more than he would have absent Defendants' unlawful scheme to prevent and delay generic entry and was injured as a result of the illegal and wrongful conduct alleged herein.

65. Plaintiff Pamela Manning is a resident of Iowa. During the Class Period, as defined below, Ms. Manning purchased and/or paid for some or all of the purchase price for Lipitor and/or its generic equivalent in the state of Iowa. Ms. Manning paid more than she

would have absent Defendants' unlawful scheme to prevent and delay generic entry and was injured as a result of the illegal and wrongful conduct alleged herein.

66. Defendant Pfizer Inc. is a corporation organized and existing under the laws of the State of Delaware. Pfizer Inc. has a place of business at 235 East 42nd Street, New York, New York 10017.

67. Defendant Pfizer Ireland Pharmaceuticals is an Irish unlimited liability company with registered offices at Operations Support Group, Ringaskiddy, County Cork, Ireland. Pfizer Ireland Pharmaceuticals is a wholly-owned, indirect subsidiary of Pfizer Inc.

68. Defendant Warner-Lambert Company is a corporation formerly organized under the laws of the State of Delaware with offices for service of process at 235 East 42nd Street, New York, New York 10017. In 1997, Warner-Lambert Company and Pfizer began co-promotion of Lipitor, and in mid-2000, Warner-Lambert Company became a wholly-owned subsidiary of Pfizer Inc. At the end of 2002, Warner-Lambert Company became a Delaware limited liability company and changed its name to Warner-Lambert Company LLC.

69. Throughout this complaint, Warner-Lambert Company and Warner-Lambert Company LLC are collectively referred to as "Warner-Lambert." The phrase "Warner-Lambert" includes, but is not limited to, Warner-Lambert employees Bruce D. Roth, Joan Thierstein, and Jerry F. Janssen.

70. Defendants Pfizer Inc., Pfizer Ireland Pharmaceuticals, and Warner-Lambert are collectively referred to as "Pfizer."

71. Defendant Ranbaxy Laboratories Limited is a corporation organized and existing under the laws of India, with a place of business located at Plot 90, Sector 32, Gurgaon -122001 (Haryana), India.

72. Defendant Ranbaxy Inc. is a corporation organized and existing under the laws of the State of Delaware, with a place of business located at 600 College Road East, Princeton, New Jersey, 08540. Ranbaxy Inc. is a wholly-owned subsidiary of Ranbaxy Laboratories Limited.

73. Defendant Ranbaxy Pharmaceuticals Inc. is a wholly-owned subsidiary of Ranbaxy Inc., with a place of business located at 9431 Florida Mining Boulevard East, Jacksonville, Florida 32257.

74. Defendants Ranbaxy Laboratories Limited, Ranbaxy Inc., and Ranbaxy Pharmaceuticals Inc. are collectively referred to as "Ranbaxy."

75. Defendants' actions, described below, were in furtherance of the alleged wrongdoing and were authorized, ordered, or performed by Defendants' officers, agents, employees, or representatives while actively engaged in the management of Defendants' affairs.

III. JURISDICTION AND VENUE

76. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1332(d) because this is a class action in which the aggregate amount in controversy exceeds $5,000,000, exclusive of interest and costs, and at least one member of the putative class is a citizen of a state different from that of one of the defendants.

77. Venue is appropriate within this district under 28 U.S.C. § 1391(b) and (c) because Defendants transact business within this district and because the interstate trade and commerce, hereinafter described, is carried out, in substantial part, in this district.

IV. LEGAL BACKGROUND

A. The Regulatory Structure for Approval of Generic Drugs and the Substitution of Generic Drugs for Brand Name Drugs

78. Under the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. §§ 301-392, manufacturers who create a new drug product must obtain the approval of the FDA to sell

the new drug by filing a New Drug Application ("NDA"). An NDA must include specific data concerning the safety and effectiveness of the drug, as well as any information on applicable patents. 21 U.S.C. § 355(a), (b).

79. When the FDA approves a brand name manufacturer's NDA, the brand manufacturer may list in the Orange Book any patents that the brand manufacturer believes could reasonably be asserted against a generic manufacturer who makes, uses, or sells a generic version of the brand name drug prior to the expiration of the listed patents. Patents issued after NDA approval may be listed in the Orange Book within thirty days of issuance. 21 U.S.C. §§ 355 (b)(1) & (c)(2).

80. The FDA relies completely on the brand name manufacturer's truthfulness about patents' validity and applicability, as it does not have the resources or authority to independently verify the manufacturer's patents for accuracy or trustworthiness.

1. The Hatch-Waxman Amendments

81. The Hatch-Waxman Amendments, enacted in 1984, simplified the regulatory hurdles for prospective generic manufacturers by eliminating the need for them to file lengthy and costly NDAs. A generic manufacturer seeking approval to sell a generic version of a brand name drug may now file an ANDA. An ANDA relies on the scientific findings of safety and effectiveness included in the brand name drug manufacturer's original NDA, but must show that the generic drug contains the same active ingredient(s), dosage form, route of administration, and strength as the brand name drug—that is, that the generic drug is bioequivalent to the brand name drug. *See* Drug Price Competition and Patent Term Restoration Act, Pub. L. No. 98-417, 98 Stat. 1585 (1984). The FDA assigns an "AB" rating to generic drugs that are bioequivalent to branded drugs.

82. The FDCA and Hatch-Waxman Amendments operate on the presumption that bioequivalent drug products containing identical amounts of the same active ingredients, having the same route of administration and dosage form, and meeting applicable standards of strength, quality, purity, and identity, are therapeutically equivalent and may be substituted for one another. Thus, bioequivalence demonstrates that the active ingredient of the proposed generic drug would be present in the blood of a patient to the same extent and for the same amount of time as the branded counterpart. 21 U.S.C. § 355(j)(8)(B).

83. Congress enacted the Hatch-Waxman Amendments to expedite the entry of legitimate generic competitors, thereby reducing healthcare expenses nationwide. Congress also sought to protect pharmaceutical companies' incentives to create new and innovative products.

84. The Hatch-Waxman Amendments achieved both goals, advancing substantially the rate of generic product launches. In 1983, before the Hatch-Waxman Amendments, only 35% of the top-selling drugs with expired patents had generic alternatives; by 1998, nearly all did. In 1984, prescription drug revenue for branded and generic drugs totaled $21.6 billion, with generic drugs accounting for 18.6% of prescriptions. By 2009, total prescription drug revenue had soared to $300 billion, with generic drugs accounting for 75% of prescriptions.

2. Paragraph IV Certifications

85. To obtain FDA approval of an ANDA, a generic manufacturer must certify that the generic drug addressed in its ANDA will not infringe any patents listed in the Orange Book. Under the Hatch-Waxman Amendments, a generic manufacturer's ANDA must contain one of four certifications. A Paragraph IV certification must state "that the patent for the brand name drug is invalid or will not be infringed by the generic manufacturer's proposed product."

86. If a generic manufacturer files a Paragraph IV certification, a brand name manufacturer has the ability to delay FDA approval of an ANDA simply by suing the ANDA

applicant for patent infringement. If the brand name manufacturer initiates a patent infringement action against the generic filer within forty-five days of receiving notification of the Paragraph IV certification, the FDA may not grant final approval to the ANDA until the earlier of (a) the passage of thirty months, or (b) the issuance of a decision by a court that the patent is invalid or not infringed by the generic manufacturer's ANDA. The FDA may grant "tentative approval," but it cannot authorize the generic manufacturer to go to market with its product.

87. As an incentive to spur generic companies to seek approval of generic alternatives to branded drugs, the first generic manufacturer to file an ANDA containing a Paragraph IV certification gets a period of protection from competition with other generic versions of the drug. For Paragraph IV certifications made prior to December 2003, the first generic applicant is entitled to 180 days of market exclusivity, which means that the first approved generic is the only available generic for at least six months. The period of approved exclusivity begins either: (1) when the first ANDA filer commences commercial marketing of the generic drug product; or (2) when a court determines that all patents which are the subject of the certification are invalid or not infringed, whichever comes first.[4]

88. As Defendants' conduct as set forth in this Complaint illustrates, brand name manufacturers may manipulate the FDA regulatory process by listing patents in the Orange Book (even if such patents are not eligible for listing) and suing any generic competitor that files an ANDA with Paragraph IV certifications (even if the competitor's product does not actually infringe the listed patent(s)) in order to delay final FDA approval of an ANDA for up to thirty months.

[4] A retroactive clause of the 2003 Medicare Prescription Drug, Improvement, and Modernization Act clarified that the "court decision" exclusivity trigger begins when an invalidity or non-infringement decision is rendered "by a court from which no appeal (other than a petition of the Supreme Court for a writ of certiorari) has been or can be taken." Pub. L. No. 108-173 § 1101(b)(3) (2003).

89. FDA regulations also permit the first generic applicant to effectively "park" its 180-day exclusivity by not commercially marketing the generic drug and by colluding with the brand name manufacturer to ensure that its patents are not invalidated. Such collusion prevents other ANDA applicants from coming to market.

B. The Benefits of Generic Drugs

90. Typically, AB-rated generics cost much less than their branded counterparts, and competition from lower-priced generics typically causes a corresponding drop in the price of the branded drug. Over time, as more generic equivalents compete with each other, prices decline even further.

91. Since passage of the Hatch-Waxman Amendments, every state has adopted substitution laws that either require or permit pharmacies to substitute AB-rated generic equivalents for branded prescriptions (unless the prescribing physician has specifically ordered otherwise). No substitution can occur until a generic manufacturer enters the market, however, which allows the brand name manufacturer to profitably charge supracompetitive prices without a material loss of sales volume. Consequently, brand name drug manufacturers have a strong interest in seeking to delay the market entry of generic competition.

92. There is an incentive to choose a less expensive generic equivalent in every link in the prescription drug chain. As a result of federal reimbursement rules and the industry pricing structure, pharmacies typically earn a higher markup on generics. Private health insurers similarly offer direct incentives to pharmacies to substitute cheaper generic products for more expensive branded ones. Health insurers are contractually obligated to pay for the bulk of their members' prescriptions, whether filled with branded or generic drugs, so they offer their members lower copays for generic drugs in order to encourage the use of generics. Members

also face the threat of increased health insurance premiums if branded prescription drug costs continue to rise.

93. Once a generic equivalent hits the market, the generic quickly overtakes sales of the branded drug. More than 90% of prescriptions for drugs that are available in both branded and generic forms are filled with a generic. The speed with which generic drugs take over the market appears to be increasing: in a sample of drugs losing patent protection between 1991 and 1993, generics held, on average, a 44% market share after one year; by 2008, generic versions would capture as much as 86% to 97% of the market within the first month of availability.

94. Branded manufacturers are well aware of generics' steady erosion of their previously monopolized market. Branded manufacturers thus seek to extend their monopoly for as long as possible, sometimes resorting, as Defendants did here, to any means possible, including unlawful conduct.

V. FACTUAL BACKGROUND

A. A Short Primer on Statins

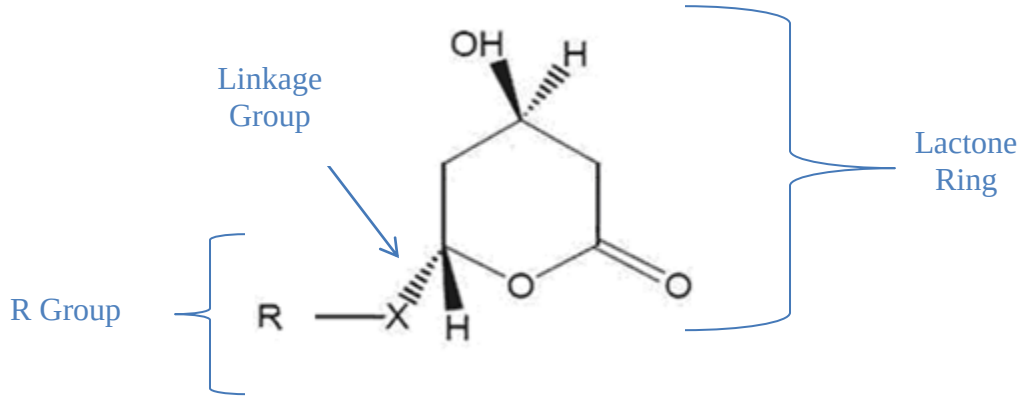
95. Lipitor belongs to a class of drugs called statins. Discovered in the 1970s, statins lower cholesterol by successfully inhibiting the liver enzyme 3-hydroxy 3-methylglutrayl-coenzyme A reductase ("HMG-CoA reductase"). HMG-CoA reductase controls the rate at which our bodies produce cholesterol; inhibiting HMG-CoA reductase reduces the production of cholesterol. High levels of cholesterol are thought to cause serious health problems in some populations, including coronary heart disease and atherosclerosis.

96. Efforts to reduce cholesterol levels are a big business: by 1997, five of the largest pharmaceutical companies sold six different brand-name statins. In 2002, almost one in ten Americans aged twenty and older took a statin. In 2004, sales of statins topped $15.5 billion, and comprised 6.6% of all prescription drug sales.

97. Branded statins cost between $2.50 and $5.00 for a single daily pill ($75 to $150 per month, $900-$1,800 per year). Generic statins cost markedly less, sometimes less than $1 per day.

98. Statins consist of three structural parts: a lactone ring, a linkage group (denoted as "X"), and a group or groups connected to the linkage group (referred to herein as an "R group").

Figure 1: Generalized Structure of Statins

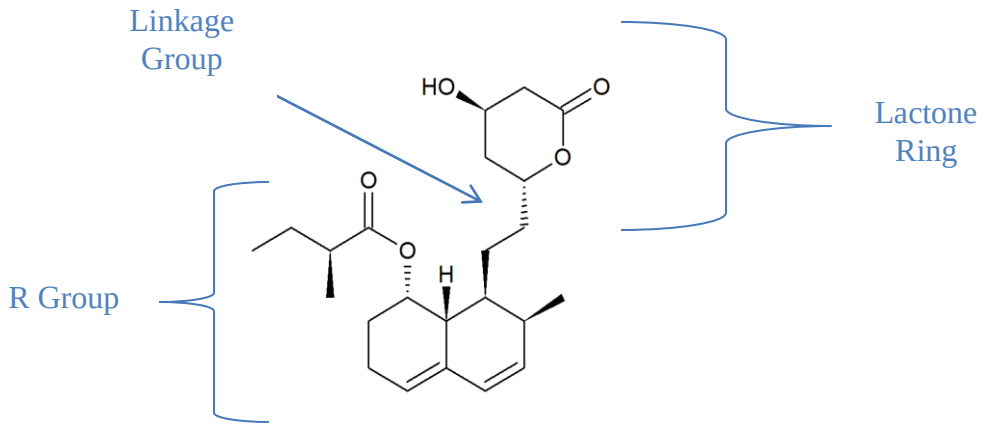


99. The R group for the well-known statins can contain one or more single rings or fused rings, along with other substituent groups.

100. In the 1970s, researchers discovered that mevastatin, naturally occurring in red yeast and rice, inhibited cholesterol synthesis.

101. Mevastatin contains the lactone ring as shown in Figure 1, a linkage group, X (shown as ), and an R group of two fused rings with substituents. One of the fused rings contains a methyl group (-CH_3, shown as ) on the right ring and an additional O-linked substituent group on the left ring.

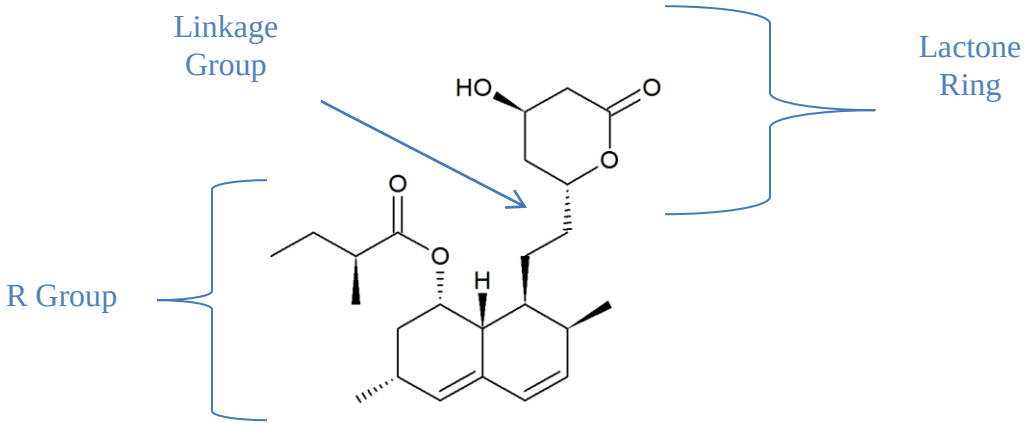
Figure 2: Mevastatin



102. Around the same time, researchers discovered that lovastatin, naturally occurring in red yeast rice and oyster mushrooms, was another highly potent HMG-CoA reductase inhibitor. In the early 1980s, Merck sought and gained approval for Mevacor, a brand name version of lovastatin, which became the first statin available in the United States.

103. The structure of lovastatin is very similar to mevastatin. Lovastatin also contains a lactone ring and an R group joined to the lactone ring by a linkage group. Lovastatin's R group is similar to mevastatin's R group but has one additional methyl group.

Figure 3: Lovastatin



104. In the early 1980s, Warner-Lambert sought to enter the market by developing a "me-too" version of the already-identified statins. Researchers at Warner-Lambert came up with a formulation that used the same lactone ring as mevastatin and lovastatin but contained different linked substituents as the R group. Warner-Lambert called their new statin "atorvastatin."

B. The Chemistry of Enantiomers

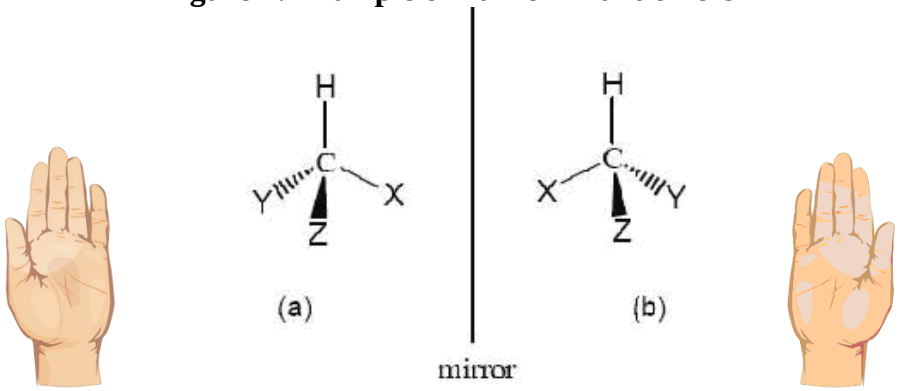
105. Some background on the chemistry of enantiomers is helpful to understand how the Original Lipitor Patent covered the compound that Warner-Lambert fraudulently sought to patent separately.

106. Isomers are two or more compounds with the same chemical formula (that is, containing the same atoms) but different arrangements of atoms. Stereoisomers are isomers in which the same atoms are bonded together, but where the three-dimensional configuration of those atoms differs.

107. Enantiomers are stereoisomers that are mirror images of each other and cannot be superimposed; they have the same atoms, bonded together in the same way, but one is arranged as a reflection of the other. Consider, for example, a left hand and a right hand.

108. Images (a) and (b) in Figure 4 below are enantiomers (where the carbon atom is the chiral center around which a compound's structure is built).

Figure 4: Example of Pair of Enantiomers



109. Pairs of enantiomers have many identical chemical and physical properties, such as shared melting points, solubility, and colors. Other properties, such as biological properties, may be vastly different.

110. Enzymes, including the cholesterol-producing HMG-CoA reductase, typically display a preference for interacting with one enantiomer over the other. It is common for one enantiomer to have all, or most, of the biological activity. The other enantiomer will have little or no biological activity.

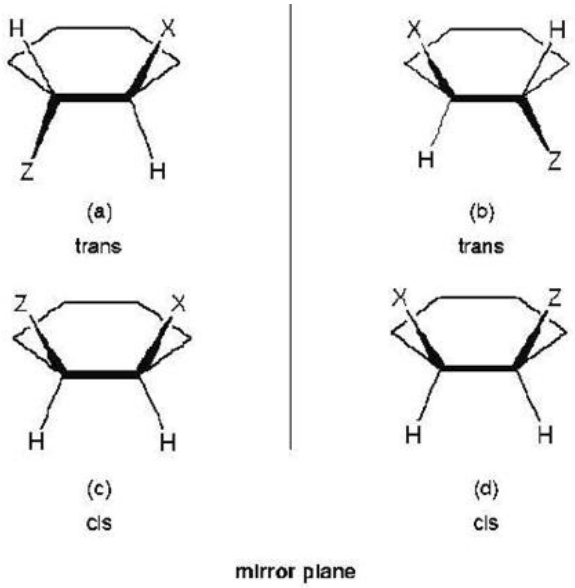
111. Enantiomers can be distinguished from one another by their effect on the rotation of polarized light. Enantiomers reflect polarized light in either a clockwise direction (right, denoted with a "+") or a counter-clockwise direction (left, denoted with a "-"). An unequal mixture of two enantiomers is optically active; the degree of optical rotation reflects the percentage of each enantiomer in the mixture. A racemic mixture or racemate exists when equal mixtures of two opposite enantiomers are present. A racemate is not optically active because the optical rotations of the enantiomers cancel each other.

112. To differentiate enantiomers on paper, each enantiomer is assigned a configuration based on priority rules that rank the atoms or substituent group of atoms that are attached to the compound's chiral center. If the priority proceeds in a clockwise direction, the

enantiomer has an "R" (right) configuration; if the arrangement is counter-clockwise, the enantiomer has an "S" (left) configuration.

113. In addition to R/S and +/- configurations, a molecule's configuration can also reference the location of the substituent atoms or groups of atoms relative to each other. An arrangement where both the major substituents lie on the same side of the plane of reference is called a *cis* arrangement. An arrangement where the major substituents appear on the opposite sides of the plane is called a *trans* arrangement. The placement of X and Z in the figure below demonstrates these cis and trans arrangements.

Figure 5: Examples of Cis and Trans Arrangements



114. The lactone rings found in statins have two chiral centers, one at the carbon atom attached to the hydroxyl group and the other at the carbon atom attached to the linkage group. Rings containing two chiral centers give rise to four possible isomers—the R-cisisomer ("R-cis"), the S-cisisomer ("S-cis"), the R-trans-isomer ("R-trans"), and the S-trans-isomer ("S-trans")—and two enantiomeric pairs—R-cisisomer & S-cisisomer and R-trans-isomer & S-trans-isomer.

115. At the time Warner-Lambert was developing Lipitor, the preferred configuration for the lactone ring in a statin—that is, the configuration offering the highest level of cholesterol inhibition—was the R-trans configuration.[5] Both mevastatin and lovastatin have lactone rings in the R-trans configuration. In the case of HMG-CoA reductase inhibitors, the R-trans enantiomer appeared to be the active enantiomer that inhibited HMG-CoA reductase and reduced the production of cholesterol.

C. Warner-Lambert Obtains the Original Lipitor Patent

116. On March 30, 1986, Warner-Lambert filed U.S. Patent Application No. 868867 for a group of compounds and pharmaceutical compositions useful as hypercholesterolemic and hypolipidemic agents. The patent application was entitled "Trans-6-[2-(3- or 4-Carboxamido-Subsituted Pyrrol-1-yl)alkyl]-4-Hydroproxypyran-2-one Inhibitors Of Cholesterol Synthesis." This application eventually resulted in U.S. Patent No. 4,681,893 (the Original Lipitor Patent).[6]

117. This lawsuit alleges that Warner-Lambert intentionally and affirmatively lied to the PTO regarding the material facts that enabled it to procure the follow-on patent as well as a later reissuance of that patent. That fraud included making misrepresentations about the Original Lipitor Patent. To understand that fraud, one must first understand the background, claims, and uses of the Original Lipitor Patent.

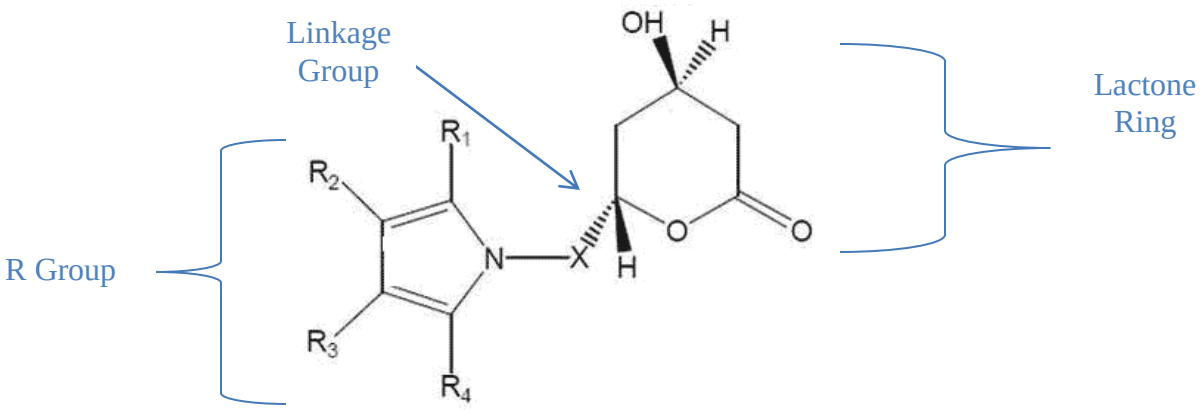
[5] *See, e.g.*, Alberts, A. *et al., J. Proc. Natl. Acad. Sci. USA* 1980, *77*:3957; Stokker, G.E., *et al., J. Med. Chem.* 1985, 28:347-358; Stokker, G.E. et al., *J. Med. Chem*, 1986, 29: 849-852.

[6] Dr. Bruce David Roth applied for the '893 Patent. Roth, who is not named as a defendant in this action, was, at all relevant times, a leader of the drug discovery team at Warner-Lambert that developed Lipitor. Roth is the named inventor and patent applicant of both the '893 Patent and the duplicative follow-on patent. Both patents issued to Roth and were assigned to his employer, Warner-Lambert. Warner-Lambert's patent attorneys, including Jerry F. Janssen, prosecuted the application.

1. The Patent Specification for the Original Lipitor Patent

118. As alleged more fully below, Warner-Lambert stated in the patent specification for the Original Lipitor Patent that "in its broadest aspect the present invention provides compounds of structural formula I."

Figure 6: Warner-Lambert's Structural Formula I



119. Like other statins, structural formula I contains a lactone ring, a linkage group (X), and an R group.

120. Consistent with conventional thinking at the time, Warner-Lambert's application for the Original Lipitor Patent contemplated the trans-form of compounds in structure formula I, including Warner-Lambert's "me-too" statin, atorvastatin. The application contemplated atorvastatin in a variety of formulations, including calcium salts.

121. Warner-Lambert claimed that the disclosed compounds were "useful as hypocholesterolemic or hypolipidemic agents by virtue of their ability to inhibit the biosynthesis of cholesterol through inhibition" of the HMG-CoA reductase enzyme. For support, the specification detailed the biological activity of three compounds as compared to the prior art.

122. Research in the 1980s had demonstrated that statin molecules with open lactone rings were highly potent cholesterol synthesis inhibitors—often more potent than the closed

lactone ring forms of the same molecules. Warner-Lambert claimed that the invention contemplated the hydroxyl acids, or structural formula I with an open lactone ring:

> Also contemplated as falling within the scope of the present invention are the hydroxyl acids, and pharmaceutically acceptable salts thereof, derived from the opening of the lactone ring of the compounds of structural formula I above.

123. Importantly, *Warner-Lambert's '893 Patent application specifies and covers a compound in which the R-trans enantiomer is isolated:*

> The compounds of structural formula I above possess two asymmetric carbon centers, one at the 4-hydroxy position of the pyran-2-one ring, and the other at the 6-position of the pyran-2-one ring where the alkylpyrrole group is attached. This asymmetry gives rise to *four possible isomers*, two of which are the R-cis- and S-cis-isomers and the other two of which are the R-trans- and S-trans-isomers. This invention contemplates only the trans- form of the compounds formula I above.

Emphasis added.

124. Neither Warner-Lambert nor Pfizer has ever disputed that the patent coverage of the Original Lipitor Patent for atorvastatin calcium included versions in which the R-trans enantiomer is isolated. As the inventor of Lipitor testified, the compounds disclosed in the '893 application and covered by the Original Lipitor Patent were not limited to any particular stereochemistry: "this one structure is meant to represent four different stereo isomers" (that is, the R-trans, S-trans, R-cis, and S-cis isomers of atorvastatin acid).

2. The PTO Issues the Original Lipitor Patent

125. On July 21, 1987, the PTO issued the '893 Original Lipitor Patent. In the absence of any extensions, the Original Lipitor Patent would have expired on May 30, 2006, twenty years from the date of the first application. Later extensions, discussed below, lengthened this period of patent protection until March 24, 2010.

126. The ’893 Patent contemplated the future ability to have only the R-trans or S-trans enantiomers of compounds of structural formula I. The ’893 Patent also recognized that these compounds could be in acid or salt form.

127. Although the ’893 Patent covered multiple formulations of structural formula I, Warner-Lambert focused on developing and commercializing atorvastatin, the R-trans enantiomer of a particular compound with structural formula I, in calcium salt form.

128. The ’893 Patent thus covered atorvastatin calcium, the product that Warner-Lambert would sell as Lipitor.

D. Warner-Lambert Fraudulently Obtains the ’995 Enantiomer Patent

129. Although the ’893 Patent would (and did) provide Warner-Lambert with many years of patent protection—and many years of exclusive sales of Lipitor—Warner-Lambert nevertheless sought to extend this monopoly by using any means, including fraud.

130. Warner-Lambert knew that the R-trans enantiomer was the active enantiomer responsible for atorvastatin’s ability to inhibit cholesterol. Warner-Lambert also knew that the PTO would reject an application to patent the enantiomer of the racemic mixture of atorvastatin because the enantiomers were already covered by the ’893 Patent; an enantiomer “invention” would either be anticipated by the ’893 Patent or obvious in light of the ’893 Patent. Thus, Warner-Lambert knew that the only way it could bypass the PTO’s restrictions and procure a follow-on enantiomer patent was to fraudulently convince the PTO that the isolated R-trans enantiomer had some “surprising” or “unexpected” characteristic.

131. Senior management at Warner-Lambert instructed the Warner-Lambert researchers to review the pre-existing biologic data for the R-trans enantiomer to come up with some data that the company could use to claim that the activity of the isolated R-trans enantiomer was “surprising” and therefore patentable.

132. Warner-Lambert senior management asked Roth whether the pure R-trans enantiomer had patent coverage. When Roth responded that the R-trans enantiomer was covered under the '893 Patent, senior management asked whether there was anything about the pure R-trans enantiomer that could make it patentable in and of itself. Roth indicated that, despite his years of work with the R-trans enantiomer, he was unaware of any such surprising characteristics.

133. Don Maxwell, Warner-Lambert's vice president of discovery research, subsequently assigned Roth the task of reviewing existing laboratory books to see whether he could find any data that could be portrayed as showing something surprising about the R-trans enantiomer. Roth was instructed to provide any surprising data to Wyeth patent attorney Joan Thierstein.

134. Regarding the instructions from these senior Warner-Lambert officials, Roth has stated,

> [I]f I found something surprising I would provide that. And what I did do was I provided that information to the patent attorney for Warner-Lambert and asked if that was sufficient, and it was and so that was the data that was used.

135. Of course, when senior Warner-Lambert management sent Roth back to the old laboratory notebooks to "find" something that could be mischaracterized as surprising, there was a wealth of knowledge in the scientific community about statins and the formulation of isolated R-trans enantiomers. This state-of-the-art understanding of statin formulations gives context to Warner-Lambert's fraud.

1. The State of the Art: Knowledge of One Skilled in the Art of Statins in 1989

136. Statins are in the field of synthetic organic chemistry as it applies to the discovery of compounds suitable for use as drugs directed to the regulation of the cholesterol biosynthetic

pathway and HMG-CoA reductase inhibitors. One of ordinary skill in the art of statins would possess at least a bachelor's degree in organic or medicinal chemistry; a general working knowledge of statins; several years of bench work in organic molecule synthesis; some general knowledge of biochemistry and enzymology; knowledge of stereochemistry of pharmaceutically active compounds; and knowledge of resolving racemates.

137. In 1989, when Warner-Lambert applied for a patent for the isolated R-trans enantiomer, one skilled in the art would have been knowledgeable about the biological pathway for the synthesis of cholesterol, including that HMG-CoA reductase is the rate-limiting enzyme in the biological pathway for cholesterol produced in an organism. One skilled in the art would also have known that statins were potent inhibitors of HMG-CoA reductase, and that the scientific literature had described *in vitro* assays as methods for testing a compound's ability to inhibit cholesterol synthesis.

138. One skilled in the art would have been aware that mevastatin (compactin) is a natural HMG-CoA reductase inhibitor that exists as a single enantiomer. One would also have been aware that lovastatin (mevinolin), another potent inhibitor of HMG-CoA reductase, had been isolated and was structurally very similar to compactin. One would also have known that both mevastatin and lovastatin have lactones in the R-trans configuration.

139. One skilled in the art would also have been aware that pravastatin (1979), symvastatin (1981), and fluvastatin (mid-1980s) were developed/isolated prior to 1989.

140. One skilled in the art would have understood that pharmaceutical research into improved inhibitors of HMG-CoA reductase was focused on analogues of known statins. One would have been aware that researchers were focused on retaining the lactone ring in known statins while investigating substitutions on the remainder of the molecule.

141. One skilled in the art would have known that the ring-opened form of the upper lactone portion of the previously discovered statins is significantly more active in inhibiting HMG-CoA reductase than the lactone (closed-ring) form.

142. One skilled in the art would have known that HMG-CoA reductase inhibitors are enantiomeric, and that one enantiomer is likely to be more active than the other. One would have known that the biological activity of a racemate in a biological system can be quite different from that of a single enantiomer, and that one enantiomer is approximately twice as active as the racemate in terms of its operation in a target biological system (*i.e.*, one enantiomer is the "active" isomer, while the other is "inactive," and thus the active enantiomer is about twice as active as the racemic mixture). One would also have known that it is desirable to separate and remove the less active enantiomer.

143. In 1989, one skilled in the art would have known that, in the case of HMG-CoA reductase inhibitors, the R enantiomer was very likely to be the active enantiomer and, conversely, that the S enantiomer was very likely to be inactive. One would have known that these expected activities could be known with certainty by isolating and testing the activity of the enantiomers.

144. One skilled in the art would have understood that racemic mixtures can be separated or resolved into the individual enantiomers by well-known methods of separation or resolution. Similarly, one would have been aware that single enantiomers can be isolated by chiral or achiral synthesis.

145. One skilled in the art would have known that it was common practice among medicinal chemists and others working in the drug discovery field in 1989 to use a single structural formula to represent both enantiomers individually, as well as mixtures of enantiomers.

One would have been similarly aware that whether a diagram depicting the structural form for a molecule or class of molecules shows a particular stereochemistry configuration (whether absolute or relative) depends on the context in which the diagram appears. One would have known that if a diagram of a single enantiomer was intended to depict a racemate, to the exclusion of the enantiomer, it was possible to add an additional descriptor, such as (+/-), RS, or (‘rac’), which would make it clear that the structure represented only a racemate.

146. One skilled in the art, given the Original Lipitor Patent, would have known that compounds in the structural formula I were racemic, that there were a discrete number of enantiomers possible from the structural formula, and that there were known methods for dissolving the racemic mixture into the enantiomers.

2. Warner-Lambert Fraudulently Claims That the R-Trans Enantiomer is Ten Times More Active than the Racemate

147. On July 21, 1989—two years to the day after the ’893 Patent issued—Warner-Lambert and Roth applied for a patent for the R-trans enantiomer, *i.e.*, for the R-trans form of the ring-opened acid described in the ’893 Patent: [R-(R*R*)]-2-(4-fluorophenyl)-β,δ-dihydroxy-5-(1-methylethyl)-3-phenyl-4-[phenylamino)carbonyl]-1H-pyrrole-1-heptanoic acid and “its lactone form and salts thereof.”[7] U.S. Patent Application No. 384187. This application would eventually lead (albeit by fraud) to the issuance of the ’995 Enantiomer Patent.

148. Warner-Lambert, including Thierstein, Anderson, and Roth, prosecuted the application from 1989 to 1993. This protracted prosecution shows the materiality of Warner-Lambert’s misrepresentations.

[7] As part of the application, Roth provided a declaration acknowledging his duty to disclose information material to the examination of the application to the PTO, pursuant to 37 C.F.R. §§ 1.56-1.63. Roth appointed Warner-Lambert’s patent attorneys as his attorneys/agents and authorized them to prosecute the application. He further directed that all correspondence related to the patent application be sent to Warner-Lambert attorney Joan Thierstein. The application itself was signed and submitted by Elizabeth M. Anderson, a Warner-Lambert employee.

149. In the application, Roth and Thierstein claimed, "[i]t is now *unexpectedly found* that the enantiomer having the R form of [a] ring-opened acid [described in the '893 Patent] . . . *provides surprising inhibition* of the biosynthesis of cholesterol." (Emphasis added). Roth and Thierstein further claimed that "an ordinarily skilled artisan may not predict the *unexpected and surprising inhibition* of cholesterol biosynthesis of the present invention in view of [prior] disclosures." (Emphasis added). In support of this contention, Warner-Lambert presented only one piece of evidence: a short table stating that Warner-Lambert's Cholesterol Synthesis Inhibition ("CSI") assay data demonstrates that the R-trans enantiomer is *one hundred-times more active* than the S-trans enantiomer, and *ten-times more active* than the racemate, in inhibiting the synthesis of cholesterol *in vitro* ("CSI Table"):

Figure 7: Specification CSI Table

is now also incorporated by reference therefor. The CSI data of the compound I, its enantiomer the compound II and the racemate of these two compounds are as follows:

Compound	IC_{50} (micromoles/liter)
[R-(R*R*)] isomer	0.0044
[S-(R*R*)] isomer	0.44
Racemate	0.045

Accordingly, the present invention is the pharmaceutical composition prepared from the compound of the formula I or II or pharmaceutically acceptable salts thereof.

150. Warner-Lambert claimed the "present invention"—the R-trans enantiomer—based on the data presented in the CSI table.

151. A CSI assay measures the ability of a compound to inhibit cholesterol biosynthesis along the entire cholesterol biosynthesis pathway and is one of the most commonly

used methods to test a compound's ability to inhibit the synthesis of cholesterol *in vitro*.[8] The results of a CSI assay are reported as an IC_{50} value, the concentration of a test compound that produces 50% inhibition in the conversion of cholesterol-[^{14}C] acetate to radioactive cholesterol. The CSI assay does not identify the specific step in the cholesterol biosynthetic pathway that is being inhibited, nor is it specific to HMG-CoA reductase.

152. One skilled in the art of statins in 1989—and indeed one skilled in the art even today—would have expected the active R-trans enantiomer to be about twice as active as the racemate in inhibiting cholesterol synthesis. After all, the racemic mixture is simply the active enantiomer combined evenly with the inactive enantiomer (and thus equal amounts of each enantiomer yield an active enantiomer that is twice as active as the mixture).

153. It would indeed be "unexpected" and "surprising" if the activity of one enantiomer were truly *ten times* that of the racemic mixture. In fact, it would be an extraordinary development in the science of stereochemistry. In reality, Warner-Lambert's claim was a deliberate misrepresentation intended to overcome the statutory limitations governing follow-on patents.

a. The CSI Table Is Misleading and Affirmatively False

154. Warner-Lambert's biologic data—the CSI Table—was both affirmatively false and presented in an intentionally misleading manner. The CSI Table purports to present reliable scientific data. It does not. Rather, it contains limited data that was cherry-picked from multiple flawed tests conducted over several years using different formulations of various atorvastatin

[8] Two other commonly used methods of measuring a compound's inhibition of cholesterol are the *in vivo* Acute Inhibition of Cholesterol Synthesis ("AICS") assay and the *in vitro* CoA Reductase Inhibition ("COR") assay. The COR assay measures a compound's ability to inhibit HMG-CoA reductase specifically and is typically used to confirm that the activity seen in the CSI assay is attributable to inhibition of the desired target: HMG-CoA reductase.

salts. The reliable data actually shows that the R-trans enantiomer is, as expected, only about two times more active than the racemic mixture—far from the "surprising" tenfold increase that Warner-Lambert claimed.

(1) The CSI Table is Misleading

155. Warner Lambert's CSI Table is misleading because it purports to present reliable and confirmed data but does not do so. The CSI Table does not disclose the source of its data and fails to indicate the number of CSI assays performed, the degree of variation in the test results, what molecules were tested, the time period over which the assays were run, or whether the results presented were drawn from multiple tests. A skilled addressee would likely conclude, therefore, the data had been confirmed by a number of repeat assays and that the CSI Table fairly depicted all relevant data.

156. Warner-Lambert claimed in subsequent litigation that the CSI Table was created by averaging the results of all available CSI screens. This, too, is not true. In fact, Warner-Lambert ran a number of CSI assays—over a multi-year period and on various salt formations—as it tested the R-trans enantiomer of structural formula I before applying for the '893 Patent. The results fluctuated wildly. Rather than averaging these assays—or offering any other valid statistical presentation of the data—Warner-Lambert cherry-picked from among the results in order to generate a table that supported its claim of "surprising activity."

157. In addition, the CSI Table combines results from a number of different CSI assays and compares them to a separate CSI assay. This was contrary to accepted scientific practice in the 1980s, which called for repeated head-to-head tests when providing data of the kind found in the CSI Table. Roth himself has repeatedly acknowledged that head-to-head testing provides the best way to compare quantitative differences in activity. However, the data presented to the PTO for the R-trans enantiomer and S-trans enantiomer were taken from a single run of the same

experiment: CSI 120. And, in bizarre contrast, the data collected for the racemate represents an "average" of five separate assays: CSI 92, CSI 93, CSI 95, CSI 102, and one of three recorded values from CSI 118.

Figure 8: Sources for Specification CSI Table

Compound	IC 50 (micromoles/liter)
R-trans Enantiomer	.0044
S-trans Enantiomer	.44
Racemate	.045

Source	Original Form	IC 50 (micromoles/liter)
CSI 120	Sodium Salt	.00444
CSI 120	Sodium Salt	.44
CSI 92	Lactone	.0346
CSI 93	Lactone	.0275
CSI 95	Lactone	.0631
CSI 102	Lactone	.0912
CSI 118	Sodium Salt	.0097

158. Moreover, the five "averaged" assays for the racemate were conducted over a three-year period from July 1985 through October 1988. Calculating an average across different days and experiments was not, and is not, consistent with accepted scientific practices. The results of these five experiments reported for the racemate are so variable that they cannot be averaged together with any reliability or scientifically meaningful result.

159. It is also inconsistent with accepted pharmaco-chemistry to "average" the results of CSI values derived from both opened lactones and separately synthesized sodium salts, as was done here. Four of the assays reflected in the racemate data in the CSI Table (CSI 92, 93, 105,

102) started with the lactone (unopened) form of racemic atorvastatin and were treated with sodium hydroxide to open the lactone ring and to create a sodium salt during the testing process. The fifth assay (CSI 118) started with chemically synthesized sodium salt of racemic atorvastatin prepared by a medicinal chemist.

160. One skilled in the art in 1989 would have been aware that if lactone rings do not fully open when exposed to sodium hydroxide, the presence of inactive material will result in a higher IC 50 value, indicating that the compound is less active than it actually is. One skilled in the art would also have expected that the IC 50 values for the racemic lactones in each of the four CSI assays would be similar, not report a four-fold difference (from .02 (CSI 93) to .09 (CSI 102)). One skilled in the art would also have expected that the IC 50 values for the racemic lactones would be similar to the value of the racemic sodium salt, not report a tenfold difference (from .009 (CSI 118) to .09 (CSI 120)). Such disparate values show that not all of the lactone rings opened during the test and/or other solubility issues that compromise the accuracy of the data. The large differences were caused by solubility differences, not by the "inherent" differences in ability to retard synthesis.

161. Notwithstanding that accepted scientific standards reject the use of the average value, the CSI Table does not even constitute a true average. As shown in Figure 9 below and although available, Warner-Lambert did not include all results from all conducted CSI assays, omitting the results from at least nine other CSI tests, including CSI 107, CSI 111, CSI 112, CSI 119, CSI 122, CSI 123, CSI 124, CSI 136, and CSI 138.

Figure 9: CSI Data (IC 50 in micromoles/liter)

CSI#	Date	Racemic Lactone	R-trans Lactone	S-trans Lactone	Racemic Sodium Salt	R-trans Sodium Salt	S-trans Sodium Salt	Racemic Calcium Salt	R-trans Calcium Salt	S-Trans Calcium Salt
92	7/24/85	.0346								
93	8/27/85	.0275								
95	10/15/85	.0631								
102	1/15/87	.0912								
107	7/20/87		.0355	.631						
111	2/25/88							.0024		
112	3/28/88							.0776		
118*	10/24/88				.00977			.257	.0251	> 1.0
					.00913			.234	.0216	
119	11/15/88							.00324		
120	2/2/89					.00498	.444			
122	4/21/89					.00313				
123	5/31/89								.00948	
124	6/12/89				.001					
136	7/31/91					.0322				
138	1/31/95					.0169				

* = test calculated multiple values using different methods.

Blue = Roth used in CSI table

Yellow = Roth reported in the Roth Declaration (discussed *infra*)

162. Depending on which assays were included or excluded, the CSI Table could have, and would have, reported very different results. For example, Roth has acknowledged that had the results of CSI 107 been included in his "average," there would be no "surprising" or "unexpected" result. Rather, had CSI 107 been included, the CSI Table would show only the

non-surprising, expected twofold increase in the activity of the R-trans enantiomer as compared to the racemate. Roth has claimed that he did not include CSI 107 because he believed that the compounds it tested were not enantiomerically pure; yet, he included the results of CSI 120, which suffered from a similar level of contamination.

163. Similarly, the CSI Table would have shown only this expected twofold increase had Warner-Lambert excluded the results of CSI 118 from its "average." As discussed below, CSI 118 suffered from myriad problems.

164. The fact remains that the R-trans enantiomer is only twice as active as the racemate, regardless of how Warner Lambert, Thierstein and/or Roth manipulated their data.

(2) The CSI Table is Affirmatively False

165. Warner-Lambert's claim that the R-trans enantiomer has surprising activity is false. Warner-Lambert's claim that the R-trans enantiomer is ten times more active than the racemate is false. Warner-Lambert, including Roth, knew that the R-trans enantiomer is, as would be expected by one skilled in the art, only about twice as active as the racemic mixture.

166. Warner-Lambert, including Thierstein and Roth, deliberately failed to tell the PTO that it possessed data that expressly contradicted representations in its patent specifications.

167. In addition to CSI assays, Warner-Lambert assessed the activity of the R-trans enantiomer, S-trans enantiomer, and the racemate through the *in vivo* AICS assay. The AICS assay—the only screen to be conducted twice and with consistent results—showed a twofold increase in activity of the R-trans enantiomer over the racemate. But Warner-Lambert never submitted the AICS data to the PTO.

168. Warner-Lambert also assessed the activity of the R-trans enantiomer, S-trans enantiomer, and the racemate through the *in vivo* COR assay. The COR data was consistent with

a twofold increase in activity of the R-trans enantiomer over the racemate. But Warner-Lambert never submitted the COR data to the PTO.

169. Warner-Lambert's own research reports conclude that the R-trans enantiomer was approximately twice as active as the racemate. A May 31, 1989 report signed by Dr. Sliskovic states that the R-trans enantiomer "was approximately *twofold* more active at inhibiting cholesterol synthesis acutely *in vivo* compared to the racemic mixture. . . . *This is to be expected* if 50% of the racemic salt is the inactive isomer." (Emphasis added). A June 1, 1989 report signed by Roth also reported a twofold increase in activity of the active enantiomer over the racemate: "[a]s expected, [the R-trans calcium salt] was twofold more potent than . . . the racemic calcium salt, which contains 50% inactive isomer." Other internal memoranda from September and December 1989 similarly conclude that, as expected, the R-trans enantiomer was twice as active as the racemate. But Warner-Lambert never shared its conclusions with the PTO.

170. Roth and Warner-Lambert knew and intended that a person skilled in the art would read the CSI Table as (1) fairly reflecting all of the appropriate CSI data available to Warner-Lambert for the relevant compounds, and (2) representing that the data as a whole provided reasonable grounds for the findings set forth in the CSI Table. Instead, Roth, Theirstein, and Warner-Lambert presented data that was affirmatively false, and intentionally presented data in a misleading manner, so that the CSI Table would be read as demonstrating a tenfold increase in activity and, therefore, support patentability.

171. Roth, Thierstein, and Warner-Lambert knew that the CSI data did not provide any "surprising" results. After all, Warner-Lambert scientists, including Roth, had conducted the various CSI assays over a period of more than three years. Certainly, if the assays had disclosed anything surprising—certainly something as shocking as a ten-fold increase in biological

activity—the scientists would have learned of the surprising results, in real time, as the tests unfolded. But none of Warner-Lamberts' internal documents (produced to date in related litigation[9]) or any of the literature published by Dr. Roth and his team concerning the discovery of atorvastatin refer to, or even suggest, a ten-fold increase in activity.

172. Instead, it was only after senior Warner-Lambert managers (not the scientists) instructed Roth to go back and "find" something surprising in the data, and after Warner-Lambert cobbled together an invalid hodge-podge analysis of different tests on different compounds, that the claimed ten-fold increase in biological activity materialized.

173. Furthermore, accepted chemistry practice in 1989 counseled to conduct controlled tests of the proposed hypothesis, *i.e.*, that there were some "surprising" attributes of the isolated R-trans enantiomer over the racemic mixture. Accordingly, if Warner-Lambert genuinely wanted to determine whether the R-trans enantiomer had any "surprising" attributes, it should have conducted *new* tests to research its hypothesis. Instead, Roth simply reviewed old data in order to create an impression, albeit a false one, of some type of "surprising" attribute.

3. The Initial Rejection: The PTO Determines the Claimed Compounds Are Anticipated By the '893 Patent

174. On March 22, 1990, pursuant to 35 U.S.C. 102(b), the PTO rejected all claims in the initial application as anticipated by (that is, covered by) the '893 Patent. The PTO determined that the '893 Patent "restrict[ed] the invention to the trans-isomers and . . . specif[ied] the R*, R* configuration. Thus, the claimed compounds, salts, compositions, and method are considered to be anticipated by [the '893 Patent]." Put simply, the PTO rejected Warner-Lambert's patent application for the isolated enantiomer because the invention was already covered by the claims in the Original Lipitor Patent.

[9] *See Ranbaxy Australia Pty Ltd. v. Warner-Lambert Company LLC*, 2006 FCA 1787 (Dec. 20, 2006).

175. The principles of "anticipation" and "non-obviousness" are distinct, but related, concepts under patent law. A proposed invention may be rejected under 35 U.S.C. § 102(b) as being anticipated by a previous patent. Alternatively, even if a proposed invention is not identically disclosed or described as set for in § 102, a patent may be rejected due to obviousness under 35 U.S.C. § 103 "if the differences between the subject matters sought to be patented and the prior art such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains." Because the patent examiner (the "Examiner") had concluded that the Original Lipitor Patent anticipated (that is, already covered) the isolated R-trans enantiomer form of atorvastatin, the Examiner did not need to reach the concept of obviousness.

176. In response to this rejection, Warner-Lambert argued against anticipation on technical grounds that the '995 Patent application addressed specific enantiomers, while the '893 Patent addressed only racemates, noting that "the presently claimed compounds are for individual enantiomers and therefore differ from the teaching in [the '893 Patent] only to mixtures of enantiomers."

177. Warner-Lambert, through Thierstein, argued that the '893 Patent did not specifically identify, and therefore did not technically "anticipate," the R-trans enantiomer:

> In molecules of the kind disclosed in [the '893 Patent], each possible isomer also exists in two forms which depend on a configuration which is expressed in absolute terms relative to the remainder of the molecule. The forms are denoted as an R form and an S form. These two forms are recognized by an ordinarily skilled artisan to be enantiomeric forms each having a specific chirality. In [the '893 Patent] the disclosure is not limited to compounds having such a specific chirality. Thus, each isomer of [the '893 Patent] is a mixture of enantiomers and not the currently claimed individual enantiomers having an R chirality.

Roth himself rejected this argument in later patent litigation.

178. The PTO issued a final rejection on anticipation grounds on November 7, 1990. The Examiner determined that the '893 Patent described the R-trans enantiomer:

> Applicant's arguments . . . have been carefully considered, but such are not persuasive. Where a reference discloses a genus or compound of similar structure which are sufficiently limited in number, the reference is deemed to provide description of those compounds just as specifically as if they were identified by name.

The Examiner observed that to isolate the claimed invention, the R-trans enantiomer, from the compounds disclosed in the '893 Patent, "one merely has to select from the limited possibility of isomers . . . and separate them using conventional techniques." Thus, the '893 Original Lipitor Patent anticipated the R-trans enantiomer.

179. Warner-Lambert abandoned the application following the final rejection on anticipation grounds.

4. The Renewed Application: Warner-Lambert Submits the Roth Declaration, Again Falsely Claiming that the R-Trans Enantiomer is Ten Times More Active than the Racemate

180. Having been rejected by the PTO once, Warner-Lambert requested a retroactive extension of time to revive its application on February 29, 1991. Included in that request was a preliminary amendment of its application and a supporting declaration from Dr. Bruce Roth ("Roth Declaration"). In it, Dr. Roth falsely professed to present evidence of an unexpected ten-fold increase in activity.[10]

181. The Roth Declaration was submitted in order to overcome an obviousness rejection and to support the patentability of the R-trans enantiomer. Accordingly, it again claims a "surprising" and "unexpected" tenfold increase in activity. It (falsely) professes to present seemingly objective evidence of an unexpected characteristic of the isolated R-trans enantiomer.

[10] The patent specification accompanying the renewed application also contained a chart (the "CSI Chart") showing that the R-trans enantiomer has ten times greater activity than the corresponding racemate. The information contained in this chart is identical to that presented in the original application.

Warner-Lambert, through Thierstein and Roth, claimed this characteristic would allow issuance of an R-trans enantiomer patent despite the fact that the claimed invention was *prima facie* obvious in light of the Original Lipitor Patent. The Roth Declaration simply presented more of the same: misleading and affirmatively false biologic data.

a. Warner-Lambert Admits that the R-Trans Enantiomer Is *Prima Facie* Obvious

182. While continuing to argue that the proposed R-trans enantiomer patent was not technically anticipated by the Original Lipitor Patent, Warner-Lambert also raised, on its own, the issue of obviousness. Indeed, Warner-Lambert admitted that the R-trans enantiomer was *prima facie* obvious in light of the '893 Patent.

183. In its remarks in support of the renewed patent application, Warner-Lambert quoted the U.S. Court of Customs and Patent Appeals in *In re May and Eddy*, 197 USPQ 601, 607 (1978): "As recognized in *In re Williams*, 36 CCPA 756, 171 F.2d 319, 80 USPQ 150 (1948), the novelty of an optical isomer is not negated by the prior art disclosure of its racemate."[11] "Clearly," Warner-Lambert asserts, "this case law is applicable here."

184. In *May*, the applicant conceded *prima facie* obviousness, but submitted "rebuttal evidence" in the form of four declarations indicating that it was "unexpected" that the compounds in question did not exhibit the addictive qualities of most opiates. The PTO refused to consider the rebuttal evidence. The U.S. Court of Customs and Patent Appeals reversed. "[B]alancing the *prima facie* case of obviousness made out by the PTO against appellants' objective evidence of nonobviousness," the court concluded, "the subject matter of claims 11-13 would not have been obvious to one of ordinary skill in the art." Thus, *May* stands for the

[11] In *Williams*, as here, the applicant sought a patent on a particular enantiomer. The *Williams* court determined that there was no evidence in the record demonstrating actual knowledge that the original patented product was racemic, and thus the idea of resolving the product into components would not have occured to one skilled in the art. In contrast, the racemic nature of the compound at issue in this litigation was well-known at the time the Original Lipitor Patent was issued.

proposition that, when a claimed invention is *prima facie* obvious, an applicant may provide declarations identifying objective evidence of a surprising characteristic to overcome an obviousness rejection.

185. Warner-Lambert purported to do just that in its renewed application, thereby conceding that the R-trans enantiomer was *prima facie* obvious. In the remarks, Warner-Lambert states:

> Following the Williams case Applicant also now provides by a declaration a comparison among each enantiomer and mixture of enantiomers. This comparison is provided to overcome the Roth reference [that is, the reference in the '893 Patent] of the present rejection to facilitate a finding of patentability and moving the prosecution toward resolution of pertinent issues. In other words, *although Examiner has not included a rejection under 35 U.S.C. 103 [for obviousness] Applicants are including a rebuttal of such rejection to comply with the Williams case law.*

(Emphasis added). Warner-Lambert further describes the Roth Declaration as "provid[ing] the data as set out in the present application in a manner to provide patentability to the application,"[12] and states, "in other words, *the declaration is submitted to provide evidence of patentability* to the instant invention." (Emphasis added).

b. The Roth Declaration is Misleading and Affirmatively False

186. Warner-Lambert submitted the Roth Declaration in an effort to overcome an otherwise inevitable rejection on obviousness grounds. The Roth Declaration states that "the antihypercholesterolemia properties of ["R-enantiomer," or "Compound I"] and ["S-enantiomer," or "Compound II"] and mixtures thereof are assessed using essentially the CSI screen that is disclosed in [the '893 Patent]." The Roth Declaration further states that the R-trans enantiomer has "activity greater than *fifty-fold more* than that of Compound II and which

[12] Warner-Lambert thus at least tacitly acknowledged that the CSI Table previously submitted in the patent specification was not sufficient to establish patentability.

indicates activity *at least ten-fold more* than that of the racemate." It also contains the following table (the "Roth Declaration Table"):

Figure 10: Roth Declaration Table

8. THAT, in said assessment, the datum from the Compound I, the datum from its enantiomer the Compound II and the datum from the racemate of the two compounds I and II are as follows:

	Compound	IC_{50} (micromoles/liter)
I	[R-(R*R*)] isomer	0.025
II	[S-(R*R*)] isomer	>1.00
	Racemate	0.26

9. THAT, the data demonstrate that the Compound I provides an IC_{50} which indicates activity greater than fifty-fold more than that of Compound II and which indicates activity at least ten-fold more than that of the racemate;

187. The Roth Declaration intentionally gives the false impression that the CSI assay data represents all reasonably available and proper information. Specifically, the Roth Declaration states that the available "datum from the compound I" (the R-trans enantiomer) and "the datum from the racemate" (the S-trans enantiomer) are presented below, implying (at minimum) that the values given reflect all appropriate, reasonably available CSI assay data. The Roth Declaration further claims that "the differences in the data . . . among Compounds I, II and racemate shows the activity of Compound I is *surprising and unexpected* because if the Compound II is accepted as inactive, the activity of the Compound I would be expected to be only twice that of the racemic mixture."[13] (Emphasis added).

188. The Roth Declaration, like the CSI Table, purports to present reliable scientific data but does not disclose the source of that data. A skilled addressee would conclude that

[13] Roth's Declaration concludes with a paragraph stating, in part, that "these statements are made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both . . . and that such willful false statements may jeopardize the validity of the above identified US patent application . . . or any patent issuing thereon."

Warner-Lambert would not have included the CSI Table in the specification in such an unqualified way unless the data had been confirmed by a number of repeat assays.

189. In fact, the Roth Declaration presents unreliable data from a single, deeply flawed screen—CSI 118—and is affirmatively false and misleading.

Figure 11: Sources for Roth Declaration Table (IC 50 in micromoles/liter)

CSI #	Date	Racemic Lactone	R-trans Lactone	S-trans Lactone	Racemic Sodium Salt	R-trans Sodium Salt	S-trans Sodium Salt	Racemic Calcium Salt	R-trans Calcium Salt	S-Trans Calcium Salt
118*	10/24/88				.00977			.257	.0251	> 1.0
					.00913			.234	.0216	

* = test calculated multiple values using different methods.

Blue = Roth used in CSI Table (discussed *supra*)

Yellow = Roth reported in the Roth Declaration

190. In addition to generating a value for the racemic sodium salt, which Roth used in the CSI Table in the patent specification, CSI 118 compared all three forms of calcium salt (R-trans, S-trans, and racemate) in a single head-to-head assay. The screen was never re-run to confirm the reported results.[14] The test results are unusable for a number of reasons.

191. First, in order to obtain accurate IC_{50} values, the concentration of the test solutions must be known prior to testing. Warner-Lambert did not determine the concentration of its test solutions prior to conducting the CSI 118 test. Without accurate information about the concentration of the solutions used in the CSI 118 test, the IC_{50} values obtained in CSI 118 are unreliable and cannot be used to demonstrate a tenfold increase in activity of the R-trans enantiomer over the racemate.

[14] Roth has admitted that he did not conduct any additional tests to confirm that the biologic data presented in the patent was in fact correct: "it is true that [the biologic data that was included in the patent] went out without any subsequent tests being asked for by me to repeat that data."

192. Second, Warner-Lambert's own lab books show that the compounds in CSI 118 did not dissolve completely in the stock solution. Using non-homogeneous suspensions can result in variations in the concentrations of the compound in the assay solution leading to wide variation in the results obtained. Given this limitation, the most that the CSI 118 results can be said to determine is whether a compound has *any* activity, not whether a compound has a twofold, threefold, or tenfold increase in activity over another compound.

193. Third, as Roth has acknowledged, an acceptable CSI test should record similar results for the racemic sodium salt and the racemic calcium salt. Yet, in CSI 118, the results of the racemic calcium salt (.257) were almost twenty-five times the results of the racemic sodium salt (.00977). The difference was so great that the IC_{50} value for the R-trans enantiomer calcium salt showed far less potency than the racemic sodium salt; that is, the R-trans enantiomer, *the active enantiomer*, of the calcium salt was *less active* than the racemate of the sodium salt. This should have alerted the scientists that something was wrong with the screen, likely a problem related to solubility issues.

194. Finally, the claim in the Roth Declaration of ten times greater activity is affirmatively false, as the activity of the isolated R-trans enantiomer is not in fact ten times greater than the racemate. Had Warner-Lambert employed a scientifically acceptable testing process, the data would have revealed that the R-trans enantiomer had, at best, a twofold advantage over the racemate.

195. Roth and Warner-Lambert were aware of the numerous problems with CSI 118 and knew that the results of CSI 118 were not scientifically sound. Yet, in the face of radically different results for the sodium and calcium salts, solubility problems, unknown solution concentrations, and results indicating that the racemate of one salt was more potent than the R-

trans enantiomer of another salt, they used this questionable and unreliable data to support the false claim that the isolated R-trans enantiomer has ten times greater inhibition of cholesterol synthesis than the racemate. They specifically claimed that this was "a surprising level of activity" which, in turn, supported patentability. Dr. Roth has admitted under oath that he submitted CSI data for the purpose of demonstrating "a surprising level of activity" which therefore supported patentability:

> Q. So [the biologic data] was put in to demonstrate this surprising level of activity for the purpose of obtaining a patent, was it not?
>
> A. [Dr. Roth:] Yes, I guess you would say that that would be true. I mean, the data supported a surprising level of activity, which we thought would be novel and surprising and therefore would support patentability.

196. Warner-Lambert knew that a person skilled in the art would read the Roth Declaration as fairly reflecting all appropriate CSI data for the relevant compounds that was available to Warner-Lambert, and as representing that the data as a whole provided reasonable grounds for the findings set forth therein. Roth and Warner-Lambert intended that the Roth Declaration be read as suggesting a tenfold increase in activity and therefore supporting patentability. In supplying the PTO with false claims, including a claim of ten times greater activity, and false and unsound data, and in packaging that data to have a false appearance of reliability, Warner-Lambert committed fraud on the PTO.

5. The Final Rejection: The PTO Determines that the R-Trans Enantiomer is Anticipated

197. The PTO Examiner issued a final rejection of the follow-on patent application on September 16, 1991, rejecting all claims as anticipated by the '893 Patent for the reasons set forth in the two rejections issued in 1990.

6. The Appeal: the Patent Board of Appeals Determines that the R-Trans Enantiomer is *Prima Facie* Obvious

198. On January 15, 1992, Warner-Lambert appealed the Examiner's rejection to the Board of Appeals, asserting that "[t]he R isomer as claimed appears to be at least *100 times more active than its corresponding S isomer and more than 10 times more active than the mixture.* Under ordinary circumstances one would have expected only a two-fold difference between the particular R isomer and the mixture." (Emphasis added). The appeal was signed by Attorney Ronald A. Daignault, a Warner-Lambert employee. Daignault states, "the present invention describes the particular R isomer which is found to have *greater than 10 times the activity* of the compound described in the prior art reference, namely, the racemic mixture," "the compound of the present invention . . . does not produce substantially the same result since it has *greater than 10 times the activity* than the reference compound," and "the R isomer is the most desired and the most *surprisingly active* isomer of the two possibilities if one is to select from the trans compounds." (Emphasis added).

199. Acknowledging that the isolated R-trans enantiomer is *prima facie* obvious over the Original Lipitor Patent, Warner-Lambert argued that the obviousness is overcome by the surprising and unexpected activity claimed in the Roth Declaration: "The examiner's rejection is erroneous as a matter of law by applying the facts of the present case to the wrong law. The issue here is whether an optical isomer is novel over its prior disclosed racemic mixture. The law as state[d] in May and Eddy affirming In re Williams says yes."

200. The Examiner filed an answer to Warner-Lambert's appeal on March 24, 1992. The Examiner alleged no new grounds for denial of the application, instead reiterating the previously disclosed grounds and stating that "even if a preferred isomer were not disclosed [by

the '893 Patent], one skilled in the art expects one of the individual isomers to be more active than the other since this, too, is knowledge contemporary in the art."

201. On October 19, 1992, the Board of Appeals overturned the Examiner's rejection of the application on the basis of *anticipation*, concluding that the '893 Patent did not technically anticipate the R-trans enantiomer:

> at best, [the '893 Patent] only describes the trans racemate containing the R-trans and the S-trans isomers in admixture. Nowhere does [the '893 Patent] state or suggest which optical isomer is preferred and, moreover, does not specifically mention how one skilled in the art could make the pure optical isomer separately. In view of the above, we are unable to subscribe to the examiner's contention that the ['893 Patent] anticipates the claimed subject matter.

202. However, the Board recommended to the Examiner that, upon remand, the patent should be rejected on the basis of *obviousness:*

> Upon further prosecution of this application before the examiner, we recommend that the examiner analyze the claimed subject matter under the provisions of § 103 of 35 USC. *An obviousness rejection of claims directed to an optically pure isomer appears to be in order when, as here, (1) the product of the prior art is known to be racemic and (2) where methods for resolving the racemic mixture into the pure optically active isomers are known to those skill[ed] in the art***.**

7. The '995 Patent Issues: PTO Relies on Biologic Data to Overcome Obviousness

203. On March 16, 1993, apparently without any further formal proceedings or briefing, the PTO issued a Notice of Allowability for the follow-on, isolated R-trans enantiomer patent application. U.S. Patent Number 5,273,995 (the '995 Enantiomer Patent) was issued on December 28, 1993.[15]

[15] Defendant Pfizer Ireland Pharmaceuticals is the exclusive licensee of the '995 Patent.

204. Warner-Lambert had presented the results of CSI screens in both the '995 Patent specification and the Roth Declaration to support its contention that the R-trans enantiomer was surprisingly and unexpectedly ten times more active than the racemate and therefore not obvious in light of the '893 Patent. Warner-Lambert made this representation in the original application for the follow-on patent, in the Roth Declaration, in its appeal to the PTO, and in the final patent specification. This representation as knowingly false when made. This is the only "surprising" activity of the isolated R-trans enantiomer that was discussed in the '995 Patent application, and it was, therefore, the sole reason that Warner-Lambert was able to overcome an obviousness rejection.

205. The PTO relied on the Roth Declaration and the CSI Table to find that the R-trans enantiomer was not obvious in light of the '893 Patent. The Board of Appeals had explicitly (i) directed the Examiner to re-evaluate the application for obviousness, and (ii) stated that an obviousness rejection appeared to be appropriate. The only "surprising" or "unexpected" characteristic of the isolated R-trans enantiomer that Warner-Lambert had claimed was the tenfold increase in activity compared to the racemic mixture. The only evidence presented in support of those claims was contained in the patent specification (the CSI Table) and the Roth Declaration, both of which, as described above, were misleading and false. Thus, upon reevaluating the application in accordance with the Board of Appeals' directive, the Examiner relied on Warner-Lambert's claim of "surprising" and "unexpected" activity and determined that the evidence presented in support of that claim (in both the patent specification itself and the Roth Declaration) were sufficient to overcome a rejection on obviousness grounds.

206. The inclusion of particular language and data in the patent specification itself confirms that the PTO relied on both the claim of "surprising" and "unexpected" activity and the

data that Warner-Lambert submitted in support of that claim. The specification states, "[i]t is now unexpectedly found that the enantiomer having the R form of [a] ring-opened acid [described in the '893 Patent], . . . that is [R-(R*R*)]-2-(4-fluorophenyl)-β,δ-dihydroxy-5-(1-methylethyl)-3-phenyl-4-[phenylamino)carbonyl]-1H-pyrrole-1-heptanoic acid, provides surprising inhibition of the biosynthesis of cholesterol." The specification further states that "an ordinarily skilled artisan may not predict the unexpected and surprising inhibition of cholesterol biosynthesis of the present invention in view of [prior] disclosures."

207. Accordingly, the '995 Enantiomer Patent would not have issued but for Warner-Lambert's fraud.

E. Warner-Lambert Intended to Deceive the PTO

208. Warner-Lambert's false claims and data were made with knowledge they were false and misleading and with the specific intent that the PTO rely on those claims in order to issue a follow-on patent. Roth and Warner-Lambert knew that a person skilled in the art would interpret the CSI Table and the Roth Declaration as representations that the results therein fairly reflected all scientifically reliable CSI data for the relevant compounds that was available to Warner-Lambert, and that the data as a whole provided reasonable grounds for the findings set forth therein. Roth and Warner-Lambert intended that the CSI Table and the Roth Declaration be read as suggesting a ten-fold increase in activity, an assertion they knew to be false, so that the documents would support the application for the follow-on patent.

1. Warner-Lambert Manipulated the Existing Biologic Data to Show a Ten-Fold Increase in Activity and Intentionally Presented False Information

209. Warner-Lambert manipulated the existing biologic data in order to show a ten-fold increase in activity. It did so with the specific intent to deceive the PTO.

210. Warner-Lambert has acknowledged that head-to-head testing provides the best way to compare quantitative differences in activity, yet it did not present such head-to-head data in support of its claim that the R-isomer has ten times the activity of the racemate. Instead, Warner-Lambert selected results from various tests conducted on different days, using different salts, and suffering from various flaws, and it presented these manipulated results in the CSI Table that was included in the patent specification. Warner-Lambert's gross departure from accepted chemistry practice—by a company fully aware of what accepted chemistry practice would have required—demonstrates Warner-Lambert's knowledge that its statements were false and its specific intent to deceive.

211. Warner-Lambert acknowledged that if it had included the results of CSI 107 in its "average," the data would not have suggested any surprising or unexpected result. Warner-Lambert has claimed that it did not include CSI 107 in its calculations because it believed that the compounds it tested were not enantiomerically pure, yet it included the results of CSI 120, which suffered from a similar level of contamination. Warner-Lambert's gross departure from accepted chemistry practice demonstrates Warner-Lambert's knowledge that its statements were false and its specific intent to deceive.

212. Warner-Lambert claimed that it did not provide the PTO with data from CSI 119 because CSI 119 was not a head-to-head comparison, and it claimed to believe that it was inappropriate to compare individual data points from different experiments. Yet, Warner-Lambert used different data points from multiple experiments to generate the data contained in the CSI Table. Warner-Lambert's gross departure from accepted chemistry practice demonstrates Warner-Lambert's knowledge that its statements were false and its specific intent to deceive.

213. Warner-Lambert included one of the three results from CSI 118 in the CSI Table in order to show an alleged ten-fold increase in activity. The sodium salt prepared by opening the racemic lactone in CSI 92, 93, 95, and 102 should have given substantially identical, or at least very similar, values to the racemic sodium salt that was separately prepared by a medicinal chemist in CSI 118. Yet, the results for the racemic sodium salt in CSI 118 differ from the results of the four lactone CSI tests by a factor of ten. Warner-Lambert's gross departure from accepted chemistry practice demonstrates Warner-Lambert's knowledge that its statements were false and its specific intent to deceive.

214. In CSI 118, the results of the racemic sodium salt and racemic calcium salt are vastly different, showing as much as a twenty-five-fold difference. The difference was so great that the IC_{50} value for the R-trans enantiomer calcium salt showed far less potency than the racemic sodium salt—that is, the R-trans enantiomer of the calcium salt was less active than the racemate of the sodium salt. This difference should have been a red flag that something was wrong with the screen, likely a problem related to the solubility of the compounds. Instead, Warner-Lambert used this questionable data to support the false claim that the R-trans enantiomer has a ten-fold greater inhibition of cholesterol synthesis as compared to the racemate.

215. Warner-Lambert was aware of the numerous problems with CSI 118 identified above, and it knew that the results of CSI 118 were not scientifically sound. Yet, in the face of radically different results for the sodium and calcium salts, solubility problems, unknown solution concentrations, and results that showed the racemate of one salt was more potent than the R-isomer of another salt, Warner-Lambert used this inconsistent outcome to further substantiate its claim that the R-isomer was ten times more active than the racemate in inhibiting cholesterol synthesis.

216. Warner-Lambert's patent attorneys submitted to the PTO the misleading and false Roth Declaration, the false and misleading Roth Declaration Table, and the misleading and false CSI Table, generated by Roth and others, in furtherance of a deliberately-planned and carefully-executed scheme to defraud the PTO in order to gain approval of the '995 Patent application

2. Warner-Lambert Admits that the Patent Specification Claims a Surprising Ten-Fold Increase in Activity

217. At numerous points in the prosecution of the '995 Patent, Warner-Lambert and Roth stated that the "surprising" characteristic of the isolated R-trans enantiomer was that it had ten-times greater than the activity of the racemic mixture. Warner-Lambert knew that both the CSI Table and Roth Declaration presented false information about the activity of the R-trans enantiomer as compared to the S-trans enantiomer and the racemate. To acknowledge in court that the only claimed "surprising" characteristic of the R-trans enantiomer was false would result in the loss of the '995 Patent and/or its foreign counterparts. Thus, in subsequent patent litigation, Roth and Warner-Lambert tried to shy away from admitting that Warner-Lambert had ever claimed that the surprising feature of the R-trans enantiomer was a tenfold increase in activity over the racemate.

218. Roth's evasive testimony on this topic is illustrative:

> Q. I suggest to you that you either do or do not rely on those figures. If you want to put out a merely qualitative statement that you have surprising activity you can put it in words. If you put it out in figures that suggests [sic] that it is a very surprising level of activity, being a 10-fold difference?
>
> A: But I believe the words we used were a surprising level of activity. We didn't say that it was surprising because it was a 10-fold difference. We simply said that it was surprising, the numbers suggest 10-fold. But frankly, again, anything more than twofold would be surprising. We didn't claim 10-fold in the patent. We said it was surprising.

Q: You didn't put a qualification to the numbers that you give in the patent to say "beware of these numbers. We're only really saying that we get a better than two-fold improvement"; no mention of that, was there?

A: What we say is that the compound has surprising activity and then we put data into the patent which supported the surprising level of activity. I don't think that we actually comment on the data except to say that it's surprising. The data is what the data is.

Q: The data on its face quantify that is surprising level of activity, does it not, Dr. Roth?

A: There are numbers given, yes.

Q: So it quantifies that surprising level of activity?

A: What do you mean by that?

Q: Do you know what the meaning of the word "quantifies" is?

A: There are numbers that are given. Again, we don't make any claims; all we say is that it's surprising. The numbers are what the numbers are.

219. Roth was ultimately forced to concede that the biologic data contained in the patent specification purports to show a ten-fold increase in activity, and that Warner-Lambert had included that data in the specification for that reason:

Q: And you wanted those numbers to be taken at face value, did you not?

A: I'm not sure I know what you mean.

Q: What?

A: The data is what the data is. The data was included to support the rising level of activity. What the numbers suggest is that it's something like 10-fold, but we don't state that. We simply – what we simply do is we say it's surprising.

Q: Isn't it a fair reading of this passage on page 8 that having said it's surprising that you are saying now here is why and you set out figures which show a 10-fold increase and you don't provide any qualification at all to those numbers?

A: That is true. We simply report the data.

220. Roth acknowledged "[t]he data is what the data is," "the numbers are what the numbers are," and that "the data was included to support the surprising level of activity. What the numbers suggest is that it's something like 10-fold . . . ." The numbers submitted to the PTO show, based on cherry-picked test results, that the R-trans enantiomer is ten times more active than the racemate. In reality, the R-trans enantiomer is, as expected, only about twice as active as the racemate.

3. Warner-Lambert Intended for the PTO to Rely on the False Data and Claims

221. Roth has admitted under oath that he submitted CSI data for the purpose of supporting a surprising level of activity which therefore supported patentability: "the biologic data that was included in the patent I felt demonstrated and supported a surprising level of biological activity."

> Q. So [the biologic data] was put in to demonstrate this surprising level of activity for the purpose of obtaining a patent, was it not?
>
> A. Yes, I guess you would say that that would be true. I mean, the data supported a surprising level of activity, which we thought would be novel and surprising and therefore would support patentability.

F. FDA Approval: The FDA approves Lipitor and the Original Lipitor Patent Provides Years of Patent Protection

222. On June 17, 1996, Warner-Lambert submitted a new drug application under Section 505(b) of the FDCA and Section 314.50 of Title 21 of the Code of Federal Regulations, seeking approval to sell atorvastatin calcium, *i.e.*, the isolated R-trans enantiomer formulated as a calcium salt. On December 17, 1996, the FDA approved atorvastatin calcium—now named "Lipitor"—for the treatment of hypercholesterolemia and mixed dyslipidemia. The FDA

initially approved 10 mg, 20, mg, and 40 mg tablets, adding approval of 80 mg tablets on April 7, 2000.

1. The Orange Book Listings for the '893 and '995 Patents

223. Following approval, Warner-Lambert listed both the '893 Original Lipitor Patent and the fraudulently-obtained '995 Enantiomer Patent in the Orange Book. When it did so, Warner-Lambert knew that it had procured the '995 Enantiomer Patent through actual fraud on the PTO.

224. Because Warner-Lambert listed both patents in the Orange Book, a generic company seeking approval for an ANDA for generic atorvastatin calcium would need to file a Paragraph IV certification as to both the '893 and '995 Patents if it wished to enter the market before the expiration of the patents. As Warner-Lambert knew and intended, this certification would trigger Warner-Lambert's ability to file infringement litigation, which in turn would trigger the Hatch-Waxman statutory delays for FDA generic approval (*i.e.*, the 30-month stay of ANDA approval).

225. At the time of FDA approval of Lipitor, the '893 Original Lipitor Patent was scheduled to expire on May 30, 2006. The '995 Enantiomer Patent would not expire until December 28, 2010.

226. The Pfizer Defendants also listed the following patents in the Orange Book as covering Lipitor: 6,126,971 (the "'971 Patent"); 5,686,104 (the "'104 Patent") (together, the "Unasserted Formulation Patents"); and 5,969,156 (the "'156 Patent"). No reasonable litigant would have had any expectation of succeeding against Ranbaxy (or any other of the significant generic manufacturers) on a claim alleging infringement of those patents. Such an infringement claim would have been an objectively baseless sham.

2. The ’893 Original Lipitor Patent Protected the Lipitor Franchise for Years

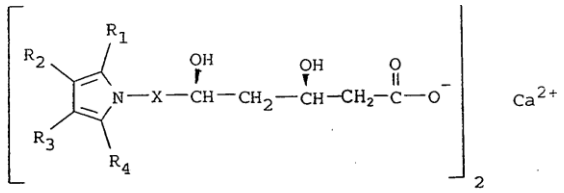
227. Shortly after FDA approval**,** Warner-Lambert applied for an extension of the patent term of the ’893 Patent under 35 U.S.C. § 156. Section 156 provides that the period of patent protection may be extended to account for the time lag between the issuance of a patent covering the active ingredient in a new drug and FDA approval of that drug.

228. Warner-Lambert asked the PTO to extend Lipitor’s period of market exclusivity granted by the ’893 Original Lipitor Patent—not the ’995 Patent—for about three years and four months. That is, Warner-Lambert took the position that the ’893 Patent covered the isolated R-trans enantiomer, atorvastatin, in calcium salt form.

229. Warner-Lambert informed the PTO that (i) the FDA approved Lipitor, (ii) the active ingredient in the drug Lipitor is atorvastatin calcium, and (iii) atorvastatin calcium is covered by the ’893 Patent. Warner-Lambert claimed that the ’893 Original Lipitor Patent claims atorvastatin calcium as a new chemical entity (Claims 1-4), as a pharmaceutical composition (Claim 8), and as a method for using it to inhibit cholesterol biosynthesis (Claim 9).

230. Claim 1 requires “a compound of structural formula I” or “a hydroxyl acid or pharmaceutically acceptable salt thereof, corresponding to the opened lactone ring of the compounds of structural formula I above.” In the extension application, Warner-Lambert claimed that Lipitor is a pharmaceutically acceptable salt of structural formula I, and is thus covered by Claim 1 of the Original Lipitor Patent:

> Lipitor is a pharmaceutically acceptable salt (i.e., calcium salt) of the hydroxy acid corresponding to the opened lactone ring of a compound of structural formula I. Lipitor has the general structure:



where: X is $-CH_2CH_2-$

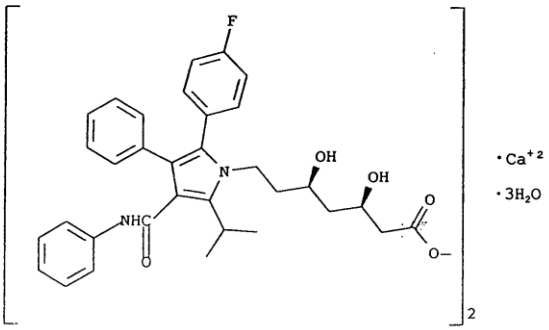
R_1 is 4-fluorophenyl;

R_2 is phenyl;

R_3 is -CONH-phenyl; and

R_4 is 1-methylethyl, an alkyl group having three carbon atoms.

Lipitor™ thus has the specific chemical structure



231. The PTO granted the patent term extension. With extensions for the delay in FDA approval and for pediatric testing, the '893 Original Lipitor Patent was to expire on March 24, 2010.

232. The Defendants also sought and obtained a six-month extension for pediatric testing for the '995 Enantiomer Patent. As a result, the expiration date of the '995 Enantiomer Patent was June 28, 2011.

233. In effect, the '893 Patent and the '995 Patent would provide almost fifteen years of patent exclusivity to market and sell branded Lipitor: the Original Lipitor Patent would provide protection from the January 1997 launch until March 2010, and the fraudulently-obtained follow-on patent (if enforced by Warner-Lambert or its successors) would tack on almost a year and a half of additional market exclusivity.

3. The 1997 Launch of Lipitor

234. Prior to commercialization, Warner-Lambert decided it wanted to employ a "saturation" approach to selling Lipitor. A 1995 sales force deployment study, however, revealed that the Warner Lambert's sales force was inadequate in size and focus to effectively launch Lipitor.

235. Warner-Lambert chose Pfizer to help market Lipitor. Between Warner-Lambert and Pfizer, more than 2,200 sales representatives were believed to be selling Lipitor at the time of its launch in the United States.

236. After launching in January 1997, Lipitor reached $1 billion in domestic sales within its first twelve months on the market. By the end of 1998, Lipitor was available for sale in fifty countries.

G. Pfizer Engages in a Campaign of Sustained Tactics to Delay Market Entry of Generic Lipitor

237. Between 2003 and 2007, Pfizer engaged in serial sham litigation against generic manufacturers that sought approval to manufacture and sell generic atorvastatin calcium. The generic pharmaceutical manufacturers that were seeking to sell generic versions of Lipitor, and which Pfizer sued for infringement of the '995 Enantiomer Patent during this period, are: Ranbaxy, Teva Pharmaceuticals USA, Inc. ("Teva"), and Cobalt Pharmaceuticals Inc. ("Cobalt"). Pfizer knew that the '995 Patent was invalid and/or unenforceable and commenced serial sham litigation to keep generic atorvastatin calcium off the market for as long as possible. Pfizer also filed a baseless citizen petition against Ranbaxy during this period in a further attempt to delay generic entry. But for the commencement of these actions by Pfizer, generic atorvastatin calcium would have been available far earlier than it was.

238. Upon information and belief, each of the generic manufacturers in the various serial sham infringement litigations received substantial consideration from Pfizer in exchange for an agreement to delay the release of their respective generic product.

1. Pfizer Files Sham Litigation Against Ranbaxy Based on the '995 Patent

239. Ranbaxy was the first to file an ANDA for generic atorvastatin calcium. Ranbaxy was also the first stymied by Pfizer's allegation that its product infringed the '995 Enantiomer Patent.

240. On August 19, 2002, Ranbaxy filed ANDA 76-477, seeking approval to sell a generic version of Lipitor. As the first to file an ANDA for generic atorvastatin calcium, Ranbaxy was entitled to 180 days of marketing exclusivity. Pursuant to the relevant provisions of the FDCA, no other ANDA applicant for generic Lipitor could receive FDA approval until the expiration of Ranbaxy's period of marketing exclusivity. The exclusivity period would not commence until the earlier of Ranbaxy's actual commercial marketing of the generic drug product or a final court decision finding that all patents listed for Lipitor in the Orange Book were invalid or not infringed.

241. On January 23, 2003, Ranbaxy sent two Paragraph IV certification letters to Pfizer with respect to all patents listed in the Orange Book, including the '893 and '995 Patents. In these letters, Ranbaxy asserted that no valid patent claims covering Lipitor would be infringed by the sale, marketing, or use of Ranbaxy's generic product.

242. On February 21, 2003, Pfizer filed an action against Ranbaxy in the United States District Court for the District of Delaware, alleging infringement of the '893 and '995 Patents. Pfizer did so within the 45-day period provided by the Hatch-Waxman statute. Pfizer did not allege infringement of the Unasserted Formulation Patents or the '156 Patent.

243. From 2003 to 2006, the infringement litigation progressed through discovery, a jury-waived trial (in 2004), a district court decision (in 2005), and an eventual appeal and decision by the United States Court of Appeals for the Federal Circuit (in 2006). Multiple factual issues for both the '893 and the '995 Patents were litigated as between Ranbaxy and Pfizer.[16] Two features of the district court proceedings are noted here.

244. First, in pre-trial proceedings Pfizer attempted to amend its complaint to add new patent infringement claims based on patent numbers 6,274,740 (the "'740 Patent") and 6,087,511 (the "'511 Patent") (the "Process Patents"). However, process patents may not be listed in the Orange Book and, therefore, could not serve as a basis for Pfizer's infringement action against Ranbaxy under the Hatch-Waxman Amendments. Accordingly, the district court denied Pfizer's motion because claims under these two Process Patents would be "premature."

245. Second, at the time the district court rendered its decision regarding the '995 Patent in December 2005, neither the district court nor Ranbaxy had the benefit of portions of critical evidence regarding Warner-Lambert's false statements to the PTO. During the Ranbaxy trial, Pfizer and Roth misrepresented several critical features of Warner-Lambert's biological testing of atorvastatin enantiomers and racemates.

246. The district court relied on these representations in finding that Roth's PTO submissions regarding the alleged ten-fold biologic power of the enantiomer over the racemate were not made with intent to deceive.

[16] Among the numerous issues litigated before the district court in the jury-waived trial between Ranbaxy and Pfizer was the early form of the evidence adduced by Ranbaxy regarding Warner-Lambert's inequitable conduct in the procurement of the '995 Enantiomer Patent. On that record, which did not include much of the evidence now available, and as between those parties, Pfizer prevailed. Of course, the Plaintiffs in this action and the proposed End-Payor Class were not parties to that litigation and are not bound by any of the determinations made therein. The issue of Warner-Lambert's representations regarding the biological activity of the R-trans enantiomer as compared to its racemate has also been litigated in other fora worldwide. There, when addressed on a more fully developed record, Pfizer lost on the issues relating to the integrity of the "surprising" data for the enantiomer.

247. Because the '995 Patent was fraudulently procured by Pfizer, and because Pfizer withheld material facts from the district court, the Ranbaxy case as to the '995 Patent was an objectively baseless sham, and was interposed merely to interfere with Ranbaxy's ability to market generic Lipitor in competition with Pfizer.

248. On August 2, 2006, the Federal Circuit reversed the district court's decision regarding the '995 Patent, determining that claim 6 of the patent (which was the only claim of the '995 Patent that the district court found Ranbaxy to have infringed) was technically invalid.[17] In light of the invalidity of claim 6, the Federal Circuit held moot the district court's other determinations regarding the '995 Patent. The Federal Circuit affirmed the district court's determination that Ranbaxy had infringed the '893 Patent and upheld that patent's time extension.

249. On remand, the district court indicated that Pfizer's market exclusivity for Lipitor extended until March 24, 2010, the date on which the '893 Patent expired. The district court removed from its Final Judgment Order any prohibition of effective FDA approval of Ranbaxy's ANDA based on the '995 Patent. On information and belief, Ranbaxy and Pfizer sent the district court's amended Final Judgment Order to the FDA.

250. In light of the Federal Circuit's invalidation of claim 6 of the '995 Enantiomer Patent, Pfizer filed with the PTO amendments to the '995 Enantiomer Patent to correct the technical nomenclature error and to obtain reissuance of the patent. Ranbaxy remained foreclosed from entering the market for atorvastatin calcium by reason of Pfizer's continued assertion that it was protected by the '995 Enantiomer Patent.

[17] More recently, the PTO accepted Pfizer's application to correct a technical defect in claim 2 of the '995 Enantiomer Patent, which would presumably repair the invalidity of claim six. In March 2009, the PTO allowed the reissue of the patent as no. RE40,667, which retained the expiration date of June 28, 2011.

251. But for Warner-Lambert's fraud in procuring the '995 Enantiomer Patent, the PTO would not have issued the '995 Enantiomer Patent. Pfizer, which acquired the license to the fraudulently-procured '995 Enantiomer Patent, used that patent to delay unlawfully Ranbaxy's entry into the market for atorvastatin calcium. Thus, but for the fraudulent procurement of the '995 Enantiomer Patent and the parties' later reverse payment settlement (discussed below), Ranbaxy would have entered the market for atorvastatin calcium far earlier than it did. Other generic manufacturers were prevented from entering the market for atorvastatin calcium by reason of Defendants' unlawful conduct and Ranbaxy's delay.

2. Pfizer Files a Baseless Citizen Petition to Further Delay Ranbaxy's Market Entry

252. As previously alleged, final approval of Ranbaxy's generic Lipitor ANDA was stayed for up to thirty months because of Pfizer's patent infringement lawsuit against Ranbaxy. The thirty-month stay ended in or about August 2005.

253. Pfizer knew that the end of the thirty-month stay would allow the FDA to issue final approval of Ranbaxy's generic Lipitor ANDA, which had been pending since August 2002. Pfizer wanted to delay the final approval for as long as possible because such approval would permit generic Lipitor competition to commence.

254. The FDA did not issue tentative approvals to ANDA filers as to whom applicable thirty-month stays had expired, at any relevant time, as a matter of procedure and practice. It only issued final approvals.

255. Ranbaxy was the sole ANDA on file for generic Lipitor as August 2005 approached. Pfizer knew and believed, based on its litigation against Ranbaxy, that Ranbaxy's ANDA proposed that its generic Lipitor drug product would use amorphous atorvastatin calcium as its active pharmaceutical ingredient.

256. On July 28, 2005, Pfizer wrote to the FDA, not for a proper purpose, but instead in an attempt to slow down the FDA approval process for Ranbaxy's ANDA following the conclusion of the thirty-month stay. As a practical matter, Pfizer had no more information about Ranbaxy's ANDA on July 28, 2005 than it had months earlier. Instead, it purposely submitted its letter to the FDA shortly before the thirty-month stay from the patent litigation was set to expire, with the hope that the FDA would continue the stay after the expiration of the original thirty-month litigation-related stay.

257. The title of Pfizer's letter to the FDA was "Generic Versions of Atorvastatin." The letter stated that Pfizer was "concerned" that ANDA applicants for generic Lipitor were using amorphous atorvastatin calcium. Pfizer's letter claimed that amorphous atorvastatin calcium "may be susceptible to higher levels of impurities than are found in Lipitor and that may degrade more quickly and thus have inferior stability compared to Lipitor."

258. The letter from Pfizer went on to state that this "may raise questions about the approval of" ANDAs for generic Lipitor. Pfizer said that "the risk of reduced quality in the generic product," due to the use of amorphous atorvastatin, was "clear," and that Ranbaxy's ANDA should be "reviewed with considerable skepticism." Based on this representation, Pfizer asked the FDA to "carefully scrutinize[ ]" such "potential differences in quality . . . before the atorvastatin variants are approved under ANDAs."

259. Pfizer was referring to Ranbaxy's use of amorphous atorvastatin calcium to circumvent Pfizer's Orange Book-listed '156 Patent, which claimed crystalline (not amorphous) forms of atorvastatin.

260. The letter to the FDA was signed by a Pfizer scientist and by a vendor Pfizer used that "provides analytical services to the pharmaceutical industry." In addition, Jeffrey B. Chasnow, a lawyer in Pfizer's legal department, was copied on the letter.

261. The FDA contacted Pfizer on August 30, 2005 to inform it that the procedure for communicating with the FDA on issues such as this was to file what is known as a "citizen petition."

262. Accordingly, on November 7, 2005, Pfizer re-filed its July 28 letter as a citizen petition ("the Petition"). The Petition reiterated Pfizer's request: "Pfizer asks that FDA consider the information provided in the July 28 letter, together with any additional information that may be submitted to the petition file by Pfizer or others, in FDA's decisions concerning approvals of generic versions of atorvastatin."

263. The FDA did not issue tentative approvals to ANDA filers when citizen petitions were pending, at any relevant time, as a matter of procedure and practice. Pfizer knew of the FDA's procedure and practice.

264. Pfizer itself used amorphous atorvastatin calcium for virtually all development activities for Lipitor, including numerous studies. Thus, while the Petition suggested that amorphous formulations should be looked at with considerable skepticism because they may be less pure and less stable than Lipitor (the drug substance of which was comprised of a crystalline formulation), Pfizer knew that safe and stable versions of atorvastatin calcium could be—and had been—made using the types of amorphous formulations that the generic manufacturers would use.

265. In or around June 1995, late in the development and prior to commercially marketing Lipitor, Pfizer switched to the crystalline form of atorvastatin calcium. However,

Pfizer did so unilaterally, not at the request of the FDA. On information and belief, Pfizer did not switch from the amorphous formulations it had been using for years based on concerns that the amorphous formulations were unsafe, ineffective, or incapable of meeting FDA requirements regarding impurities or stability. Rather, Pfizer did so in anticipation of the issuance of the '156 Patent, which claimed crystalline forms of atorvastatin.

266. Thus, because Pfizer had thoroughly studied the amorphous form, in or around June 1995, it knew and therefore told the FDA that there were no clinical safety or efficacy implications related to using the amorphous, as compared with the crystalline, form. Indeed, it turned out that toxicity was a concern for the *crystalline* form of atorvastatin calcium that Pfizer ultimately used, not the amorphous form that Pfizer abandoned and Ranbaxy proposed to use.

267. Pfizer submitted no evidence to the FDA that showed or even suggested that Ranbaxy's use of amorphous atorvastatin calcium as the drug substance in its ANDA product: (a) was not (or would not be) pharmaceutically equivalent or bioequivalent to branded Lipitor; (b) could not or would not demonstrate satisfaction of the conditions for approval under the FDCA; and/or (c) could not or would not be capable of being processed or manufactured under current good manufacturing practices ("cGMP").

268. Pfizer, instead, submitted its Petition in contradiction to the FDA's prior stated positions concerning polymorphism.

269. In 1992, approximately thirteen years before Pfizer submitted its Petition, the FDA specifically rejected a regulatory proposal that would have required an ANDA applicant to show that the active ingredient (*i.e.*, the drug substance) in its generic drug product and the active ingredient in the corresponding brand drug "exhibit the same physical and chemical characteristics, that no additional residues or impurities can result from the different manufacture

or synthesis process, and that the stereochemistry characteristics and solid state forms of the drug have not been altered" (the "1992 Regulatory Rejection"). Thus, more than a decade earlier, the FDA had already determined that differences in drug substance polymorphic forms, including differences in residues and impurities, do not cause drug substances to be considered different active ingredients for the purposes of ANDA approvals within the meaning of the FDCA and FDA regulations.

270. In fact, Pfizer had actual and/or constructive knowledge of a February 15, 2002 publicly-available denial of another company's citizen petition (the "2002 Decision"). In that decision, the FDA stated that the "FDA's view is that the [FDCA], existing regulations, preamble statements, and the FDA publication *Approved Drug Products With Therapeutic Equivalence Evaluations (Orange Book)* [already] provide an adequate basis to guide the Agency's decision-making on ANDAs seeking approval of a generic drug product whose active ingredient has a different physical form than the active ingredient in the reference listed drug." The generic ANDA filer in the 2002 Decision was, as here, Ranbaxy. Thus, more than three years before Pfizer sent its letter to the FDA, the FDA had already declined to utilize special or additional scrutiny or specifications when reviewing ANDAs for drug products that utilized different polymorphic forms of the active pharmaceutical ingredient.

271. In its 2002 Decision, the FDA expressly declined to apply special or additional scrutiny or specifications to the review of an ANDA when a different form of the active pharmaceutical ingredient was used by the proposed ANDA product. Specifically, the FDA ruled that its "review of any ANDA [already] includes ensuring that the ANDA applicant has the appropriate controls in place with respect to the drug substance and drug product. In FDA's view, Ranbaxy has appropriate controls with respect to the drug substance and the drug product."

272. In the 2002 Decision, the FDA explained that under existing FDA standards, what mattered in connection with ANDA approval was the performance of the drug product (not the active ingredient (*i.e.*, the drug substance in isolation)):

> If a polymorph displays different properties such as melting point, solubility, and stability, these characteristics could ultimately have an impact on the approval of an ANDA for a proposed generic drug product. These characteristics could ultimately affect the approval because the approval is based not only on whether the active ingredient in the proposed generic drug product is the "same" as the active ingredient in the reference listed drug, but also on whether the proposed generic drug product is the same as the reference listed drug. FDA will approve a generic drug product if the ANDA applicant provides, among other things, sufficient information to show that the generic drug product is the "same" as the reference listed drug. However, if the active ingredient of a proposed generic drug product were to have a different polymorphic form than the active ingredient in the reference listed drug, and this difference affected the behavior or certain characteristics of the drug product, then FDA might not approve the generic drug product, despite the fact that the proposed generic drug product contained the same active ingredient as the reference listed drug.

273. In the 2002 Decision FDA also announced that:

a. "[a] difference in the physical form of an active ingredient in a generic drug product from the physical form of the active ingredient in the reference listed drug, including a difference in the crystalline structure of the active ingredient, does not bar the approval of a proposed generic drug product";

b. "[f]or a generic drug product to be regarded as having the same active ingredient under [21 C.F.R] § 314.92(a)(1), the drug substance in a proposed generic drug product need not have the same physical form as the drug substance in the reference listed drug"; and

c. "FDA's scientific expertise and experience have shown that a difference in the physical form of the active ingredient in a generic drug product from the physical form of the active ingredient in the reference listed drug, including a difference in the crystalline structure of the active ingredient, does not prevent a finding of therapeutic equivalence."

274. Indeed, preeminent scientists within the FDA's Center for Drug Evaluation and Research were publicly stating, since at the latest 2003, that there was "no scientific basis" upon which to conclude that an ANDA applicant's use of a different drug substance polymorph, compared with the corresponding brand drug, would prevent the ANDA applicant from demonstrating drug product bioequivalence, stability, and manufacturability. At or around the same time, those same FDA scientists also stated that there was "no scientific or regulatory basis" for requiring a generic drug product to use the same polymorphic form as the innovator.

275. At or around the same time, those same FDA scientists also stated that despite the potential effect that polymorphism may have on drug stability, "drug product stability is affected by a multitude of other factors, including formulation, manufacturing process, and packaging." As a result, they explained that "it is the stability of the drug product, not the drug substance that is the most relevant measure of drug quality." Thus, according to the FDA, existing FDA scrutiny of ANDAs was sufficient when polymorphic forms of drug substances were involved. The FDA scientist said, "under cGMPs, the sponsor of the ANDA must still provide evidence of manufacturing process validation and demonstrate that the drug product can be manufactured reproducibly, while meeting all the required in-process, release, and stability specifications."

276. In draft Guidance issued in December 2004 (the "2004 Polymorph Draft Guidance"), the FDA explained that existing FDA regulations and ANDA review procedures already accounted for polymorphism:

> In addition to meeting the standards for identity, each ANDA applicant is required to demonstrate that, among other things, the drug product exhibits sufficient stability and is bioequivalent to the [corresponding brand drug]. While the polymorphic form can affect drug product stability and bioequivalence, these performance characteristics are also dependent on the formulation, the manufacturing process, and other physicochemical properties (*e.g.*, particle size, moisture) of both the drug substance and formulation excipients. Using a drug substance polymorphic form that is different from that of the [corresponding brand drug] may not preclude an ANDA applicant from formulating a generic drug product that exhibits bioequivalence and stability, and the drug substance in the generic drug product need not have the same polymorphic form as the drug substance in the [corresponding brand drug].

277. Thus, in its 2004 Polymorph Draft Guidance, the FDA reiterated what the FDA scientists had said in 2003: "because drug product stability is affected by a multitude of other factors, including formulation, manufacturing process, and packaging, it is the stability of the drug product, and not stability of the drug substance polymorphic form that should be the most relevant measure of drug quality."

278. Pfizer did not comment on the 2004 Polymorph Draft Guidance, despite being given the opportunity to do so.

279. The preface to the Orange Book provided that "[a]nhydrous and hydrated entities, as well as different polymorphs, are considered pharmaceutical equivalents," and did so at all relevant times.

280. Prior to sending its July 2008 letter and Petition to the FDA, Pfizer had actual and/or constructive knowledge of the FDA's foregoing expressed views regarding polymorphic forms of active pharmaceutical ingredients.

281. The letter and Petition were interposed solely to create an obstacle to the final FDA approval of Ranbaxy's generic Lipitor ANDA. No objectively reasonable petitioner would have expected success on the merits of Pfizer's July 28, 2005 letter or its November 7, 2005 Petition. Pfizer's letter and Petition lacked any reasonable regulatory, scientific, medical, or other rational basis. Pfizer's letter and Petition lacked any evidence that provided support to its assertions or that reflected on the approvability of Ranbaxy's ANDA product. Pfizer's letter and Petition had no possibility of affecting FDA policy or procedure. Indeed, Pfizer's letter and Petition was flatly contrary to the FDA's expressed views regarding drug substance polymorphic forms, and did not reasonably argue, or argue at all, for a change in those expressed views. In short, Pfizer's letter and Petition were nothing more than a thinly-veiled effort to delay the FDA from granting final ANDA approval for Ranbaxy's product.

282. The FDA issued its formal written denial of Pfizer's Petition on November 30, 2011, the same date on which Ranbaxy could first enter the market with generic Lipitor pursuant to its settlement with Pfizer.

283. The FDA denied Pfizer's Petition because ANDA applicants need not show that the active ingredients in their drugs have no additional residues, impurities, or solid state forms relative to the active ingredient in the corresponding brand drug. The basis for the denial was not surprising given that it was in line with what the FDA had already stated in the 1992 Regulatory Rejection, the 2002 Decision, the 2004 Polymorph Draft Guidance, and repeatedly thereafter.

284. As the FDA has stated repeatedly before, the FDA's existing policies and procedures were adequate to identify any ANDA product which used different polymorphs than the corresponding brand product, determine whether that difference resulted in any differences in measures such as purity or stability, and, if such differences existed, whether the purity and stability data for the ANDA product satisfied the FDA's longstanding standards for such measures. Nothing about this process required any additional skepticism or special consideration by the FDA. Accordingly, the FDA again expressly declined to apply special or additional scrutiny or specifications to the review of such ANDAs:

> We believe that the Agency's existing recommendations to industry on assessing active ingredient sameness and stability of polymorphic forms of drug substances, as well as those on comprehensive chemistry, manufacturing, and controls (CMC) and impurities, are adequate to enable an ANDA applicant to address any potential drug product stability, degradation, and impurity issues associated with the amorphous form of atorvastatin. We also believe that the Agency's existing policies and review practices are sufficient for a critical evaluation of the variables that have the potential to affect drug product quality of drug products containing amorphous atorvastatin**.**
>
> * * *
>
> In the preamble to the final rule implementing the generic drug approval provisions of the Hatch Waxman Amendments, FDA specifically rejected the suggestion that the Agency adopt a requirement that active ingredients "exhibit the same physical and chemical characteristics, that no additional residues or impurities can result from the different manufacture or synthesis process; and that the stereochemistry characteristics and solid state forms of the drug have not been altered."

285. Moreover, the FDA again stated in denying Pfizer's Petition, just as it had done in the 2004 Draft Polymorph Guidance, that **"the inherent stability of the *drug substance* polymorphic form should not be the primary consideration in making a determination of**

***product* stability. Rather, the stability of the generic atorvastatin drug *product* is the most relevant measure of drug product quality"** (Emphasis in original).

286. Pfizer's Petition was flatly contrary to, and willfully ignored, the FDA's previous decisions and previously-expressed views in the 1992 Regulatory Rejection, the 2002 Decision, the 2004 Polymorph Draft Guidance, and repeatedly thereafter. Pfizer had no objectively reasonable basis to file the letter or Petition, given those previous FDA decisions and previously-expressed views.

3. Pfizer Files Sham Litigation Against Teva Based on the '995 Patent

287. On April 24, 2007, Teva notified Pfizer, pursuant to the Hatch-Waxman Amendments, that it had filed ANDA 78-773 seeking approval to sell a generic version of Lipitor. Teva included a Paragraph IV certification that the '995 Enantiomer Patent was invalid, unenforceable, or would not be infringed by Teva's proposed generic product.

288. On June 7, 2007, Pfizer responded by filing an action against Teva in the United States District Court for the District of Delaware, alleging infringement of the '995 Patent (excepting claim 6). The parties reached a settlement of this action on July 15, 2009, whereby, upon information and belief, Pfizer gave substantial consideration to Teva in exchange for Teva's agreement to not seek approval for its generic product for a certain period of time.

289. But for Warner-Lambert's fraudulent procurement of the '995 Enantiomer Patent and the parties' reverse payment settlement, Teva would have entered the market for generic atorvastatin calcium in or about September 2010 (the month in which Ranbaxy's period of generic market exclusivity would have expired had it entered the market upon the expiration of the '893 Patent) or earlier.

4. Pfizer Files Sham Litigation Against Cobalt Based on the '995 Patent

290. At some time prior to December 2007, Cobalt notified Pfizer, pursuant to the Hatch-Waxman Amendments, of its application seeking FDA approval to market atorvastatin and its Paragraph IV certification that the '995 Enantiomer Patent was invalid, unenforceable, or would not be infringed by Cobalt's proposed generic product.

291. On December 6, 2007, Pfizer filed an action against Cobalt in the United States District Court for the District of Delaware, alleging infringement of the '995 Enantiomer Patent (excepting claim 6). In consenting to judgment on May 15, 2008, Cobalt admitted that the '995 Patent would be infringed by the product proposed in its ANDA. The consent also restricted the effective date of any approval of Cobalt's ANDA to be no earlier than the expiration of the '995 Patent. Upon information and belief, Pfizer gave substantial consideration to Cobalt, including the exclusive right to sell an "authorized generic" upon market entry of other generics, in exchange for Cobalt's agreement to not seek approval for its generic product for a specified period of time.

292. In 2009, Watson Pharmaceuticals acquired Cobalt and the right to market Pfizer's "authorized generic" version of Lipitor.

293. But for Warner-Lambert's fraudulent procurement of '995 Enantiomer Patent and the parties' reverse payment settlement, Cobalt (or its acquirer, Watson) would have launched a generic formulation of atorvastatin calcium in or about September 2010 (the month in which Ranbaxy's period of generic market exclusivity would have expired had it entered the market upon the expiration of the '893 Patent) or earlier.

H. Under the Guise of Meritless "Process Patent" Litigation, Pfizer and Ranbaxy Conspire to Divide Markets and Cause Reissuance of the '995 Patent

294. By 2008, a markedly changed landscape afforded Pfizer no practicable opportunities to unilaterally extend its marketing exclusivity for Lipitor beyond March 2010: (i) the '995 Patent would expire in March 2010, (ii) Claim 6 of the '995 Patent (the only asserted claim against Ranbaxy) was adjudicated invalid, (iii) its effort to gain re-issuance of the '995 Patent had been met with protests by Ranbaxy and rejections by the PTO, (iv) its two process patents could not apply to Ranbaxy's product (and would likely not apply to other generic efforts), (v) its two stabilization formulation patents had never been, and could never be, asserted against Ranbaxy (and likely any other generic company), (vi) the petition it had filed with the FDA lacked all merit and would, in time, be rejected, and (vii) the PTO had rejected the '995 reissuance application and there was no reason to think it would change its mind in the face of Ranbaxy's informed opposition.

295. On March 24, 2008, Pfizer instituted a *second* action against Ranbaxy, citing a February 28, 2003 letter from Ranbaxy informing Pfizer of Ranbaxy's filing of ANDA 76-477 in connection with the '995 Patent. This time, Pfizer's lawsuit focused on the Process Patents (*i.e.*, the '740 Patent and the '511 Patent), which cover *processes* for making atorvastatin calcium.[18] As process patents, neither of these patents are listed in the Orange Book, and thus do not implicate the usual paragraph certification and statutory stay provisions of the Hatch-Waxman Amendments.

296. This second infringement lawsuit, in which Pfizer sought to enjoin Ranbaxy from infringing the Process Patents (claims that the first infringement court refused to allow), was sham litigation intended to operate as a cover for the reverse payment "pay-for-delay" agreement

[18] The Process Patents are both scheduled to expire on July 16, 2016.

(the "Agreement") between Pfizer and Ranbaxy. The parties could not agree to allocate the market outside of ongoing patent litigation without the Agreement being considered a blatant antitrust violation, including under the per se violation doctrine.

297. There was no risk to Ranbaxy and no real case or controversy involved in this second patent infringement litigation because the parties knew that there was no imminent (or even realistic) threat of injury under the asserted patents; this point had already been decided in the first infringement litigation and Pfizer was well-aware that Ranbaxy could—and would—manufacture its generic Lipitor product in a way that did not infringe the Process Patents.

298. Pfizer knew or believed that Ranbaxy's first-filer status gave it the opportunity to market its version of generic Lipitor free of competition for 180 days. This 180-day exclusivity gave Ranbaxy the ability to prevent generic competitors from entering the market: Ranbaxy could thwart competition by waiting to launch its version of generic Lipitor or by surrendering its right to the 180-day exclusivity period. Pfizer was well aware of Ranbaxy's ability to exclude competition.

299. This provided Pfizer with a unique opportunity to delay competition from generic Lipitor. By agreeing with Ranbaxy to delay the launch of its generic Lipitor, they could (and did) create a bottleneck that for the duration of the Agreement that foreclosed competition from all other ANDA filers.

300. Pfizer also wanted to obtain reissuance of the '995 Patent, which had been tarnished by the technical invalidation of claim 6. At the time Pfizer first brought the Process Patent litigation, Ranbaxy was protesting against Pfizer's application for reissuance of the '995 Patent. While Ranbaxy pursued its protest before the PTO, the PTO continually rebuffed Pfizer's efforts to obtain reissuance of the '995 Patent. Pfizer knew at this time that its efforts to

obtain reissuance of the '995 Patent were unjustified under *any* reading of the facts and the law, and that the PTO, educated by Ranbaxy's input, would continue to refuse reissuance.

301. Moreover, when assessing its strategic options, Pfizer knew that it could not use its Unasserted Formulation Patents (*i.e.*, the '971 and '104 Patents) or the '156 Patent to prevent Ranbaxy's market entry. Neither of the Unasserted Patents had yet been used as the basis for an infringement action against Ranbaxy, nor could they. Both patents were for narrow formulations to achieve stabilization for particular atorvastatin drug products, and thus neither of them applied to Ranbaxy's proposed product. As to the '156 Patent, it covered crystalline forms of atorvastatin, not amorphous ones (such as Ranbaxy's product). Pfizer did not and could not show that Ranbaxy's product would infringe the Formulation Patents or the '156 Patent, and as of today, Ranbaxy's product is presumed not to infringe these patents.

302. On June 17, 2008, only 11 weeks after the action was filed, Ranbaxy and Pfizer entered into a reverse payment "pay-for-delay" settlement—the Agreement. The parties agreed that Ranbaxy would be enjoined from engaging in the manufacture, use, or sale of generic Lipitor until November 30, 2011. As discussed more fully below, the Agreement involved "payment[s] from a patent holder to a generic patent challenger who agrees to delay entry into the market." *In re: K-Dur Antitrust Litig.*, 2012 U.S. App. LEXIS 14527, *49 (3d Cir. July 16, 2012).

1. Pfizer's Process Patent Litigation Against Ranbaxy Was Meritless as a Matter of Fact and Law

303. It was objectively clear to a reasonable litigant, and both Pfizer and Ranbaxy subjectively knew, that the Process Patents could not and would not exclude Ranbaxy from manufacturing and marketing generic Lipitor. Pfizer could not realistically expect to meet its burden of showing that Ranbaxy would infringe the Process Patents.

304. Salts of atorvastatin are polymorphic, and thus are either crystalline or amorphous. The crystal lattice contains different arraignments or confirmations of molecules. However, the crystal lattice of amorphous forms are made up of disordered arrangements of molecules and therefore are not distinguishable.

305. The patent specifications in the Process Patents are nearly identical. In fact, the Summary of the Invention sections of the '740 Patent and the '511 Patent are identical, stating, in relevant part, as follows:

> [T]he present invention is a novel process for the preparation of amorphous atorvastatin and hydrates thereof which comprises:
>
> (a) dissolving crystalline Form I atorvastatin in a non-hydroxylic solvent; and
>
> (b) removing the solvent to afford amorphous atorvastatin"

306. Thus, for a generic manufacturer's process to infringe either of the Process Patents, the generic manufacturer must at least begin by dissolving crystalline Form I atorvastatin in the specified solvent. If the manufacturing process dissolves into the solution any crystalline structure which is not Form I, or dissolves amorphous atorvastatin into the solution, the process will not infringe either of the Process Patents. An infringing process must also meet each of the other claims of the Process Patents.

307. A large number of non-infringing alternatives existed to the technology claimed in each process patent. This was a result of the narrow scope of the Process Patents and the ample number of available amorphous and crystalline forms of atorvastatin. In fact, before developing crystalline formulations such as Form I, Pfizer itself had manufacturing processes that produced amorphous atorvastatin. Thus, anyone seeking to produce amorphous atorvastatin calcium would not need to first produce Form I crystalline atorvastatin calcium.

308. As Pfizer knew, generic manufacturers sought to—and did—develop generic atorvastatin formulations that could be manufactured without infringing the formulation patents or the Process Patents. Indeed, Pfizer knew that generic manufacturers conduct patent searches to target brand name drugs covered by patents that they can easily design around or invalidate.

309. Process patents cannot be in listed in the FDA's Orange Book because they do not claim an approved drug itself or the approved use of a drug. Therefore, Pfizer would have been unable to trigger a thirty-month stay of the FDA approval of an ANDA through infringement litigation relating to the Process Patents. In other words, there was no regulatory issue related to the Process Patents that would impede generic entry.

310. In addition, the numerous non-infringing alternatives to the processes claimed in the Process Patents meant that Pfizer was unable, on the basis of the Process Patents, to obtain a court order enjoining ANDA filers, including Ranbaxy, from selling generic versions of Lipitor on the basis that they infringed the Process Patents. Thus, there was no tangible legal impediment to generic entry into the market for Lipitor based on infringement of the Process Patents.

311. Given these facts, it is unsurprising that Pfizer's March 24, 2008 complaint concerning the Process Patents contained nothing more than conclusory allegations. There were no factual allegations describing how Ranbaxy's future manufacturing process would infringe the various claims of the Process Patents. Instead the complaint simply states:

> 30. Upon information and belief, Ranbaxy's Atorvastatin Product is made or is intended to be made by a process which if practiced in the United States would infringe the '511 patent.

* * *

> 41. Upon information and belief, Ranbaxy's Atorvastatin Product is made or is intended to be made by a process which if practiced in the United States would infringe the '740 patent.

312. These allegations are objectively baseless both as a matter of law and fact. No reasonable litigant would believe that Ranbaxy was unaware of the elements of the Process Patents or that Ranbaxy was incapable of, or unwilling to, avoid infringing the Process Patents. The forms of atorvastatin are numerous and Ranbaxy, upon information and belief, used a form other than the crystalline Form I claimed by the Process Patents, at the start of its manufacturing process. Ranbaxy could create an amorphous form of atorvastatin without the need to first create a crystalline form of atorvastatin calcium.

313. Prior to filing the complaint, Pfizer was aware that Ranbaxy had intended to use amorphous atorvastatin as starting material to manufacture generic Caduet, another atorvastatin drug. It was clear that Ranbaxy would use a similar non-infringing amorphous atorvastatin, or that it would use one of the many of the other non-infringing forms of atorvastatin, to manufacture its generic Lipitor.

314. During the pendency of the Process Patent litigation, Pfizer never produced any evidence to support its purely conclusory allegations that Ranbaxy would infringe the Process Patents.

315. Finally, as Ranbaxy argued in its motion to dismiss, the lawsuit involving the Process Patents was legally meritless because, among other reasons, the court lacked subject matter jurisdiction under the Declaratory Judgment Act. Specifically, there was no Article III case or controversy: Ranbaxy was not violating the Process Patents (which would necessarily require actual *current* production of a product) at the time of the suit, and Ranbaxy was

enjoined—by virtue of the Final Judgment Order concerning the '893 Patent—from manufacturing an infringing product for another two years.

2. The Agreement in Action

316. Despite the resulting inability to sell generic Lipitor until more than twenty months after the '893 Patent was set to expire, and five months after the fraudulently-obtained '995 Patent would expire, *if* it was to reissue, and despite the objective and subjective baselessness of the Process Patent litigation, Ranbaxy nonetheless agreed to abstain from marketing a generic version of Lipitor in the United States until November 30, 2011. The Agreement also called for Ranbaxy not to selectively waive or relinquish its first-to-file 180-day exclusivity, thereby foreclosing any other ANDA filer from competing against Pfizer with a generic Lipitor until November 30, 2011. Absent the Agreement and in light of the enormous profit opportunity that generic Lipitor presented, Ranbaxy would have been highly motivated to pursue either of these courses far earlier.

317. Ranbaxy was well-compensated for agreeing to keep its generic version of Lipitor off the market beyond the time when Pfizer could have legitimately excluded Ranbaxy. Upon information and belief (and the limited public information about the agreement), Ranbaxy received at least the following for its cooperation: (1) permission to sell generic versions of Lipitor in at least eleven foreign markets, including Canada, Belgium, Netherlands, Germany, Sweden, Italy, and Australia, and the significant and ongoing revenues and profits it received from the grant and exercise of such generic Lipitor sales and marketing rights; and (2) forgiveness of money judgments obtained by Pfizer for infringement claims unrelated to the Process Patents, the Unasserted Formulation Patents, and/or the '156 Patent. Absent Pfizer's compensation to Ranbaxy, Ranbaxy would not have agreed to any delay of its launch (or to any delay of its authorizing another ANDA filer to launch). At a minimum, absent the compensation

to Ranbaxy, Ranbaxy would not have agreed to delay its launch (or to delay its authorizing another ANDA filer to launch) for as long as it did, and would instead have agreed only to a substantially shorter period of time before which it would enter.

318. The Agreement also ostensibly gave Ranbaxy protection from infringement liability in connection with a variety of patents that purportedly covered atorvastatin. However, that "consideration" was a sham, illusory, and merely inserted into the Agreement to disguise the illegal horizontal agreement to allocate the entire United States market for atorvastatin calcium.

319. In exchange, the Agreement called for Ranbaxy not to challenge the validity of any Lipitor patent, including the '995 Patent. Ranbaxy also agreed to drop its challenge to the reissue proceedings in front of the PTO.

320. After Ranbaxy dropped its protests to reissuance, the PTO reissued the '995 Patent as the '667 Patent and, like the '995 Patent, the '667 Patent was set to expire on June 28, 2011. Pursuant to its agreement with Pfizer, Ranbaxy would not market its generic version of Lipitor until November 30, 2011, more than five months after the '667 Patent expired.

321. The Agreement between Pfizer and Ranbaxy was unlawful, as Pfizer provided consideration to Ranbaxy in exchange for Ranbaxy's agreement to delay generic market entry, and there were no countervailing procompetitive justifications for the settlement that could not have been achieved in another manner.

322. The Agreement also restricted competition in a manner that exceeded the exclusionary reach of Pfizer's Lipitor patents. Neither the '995 nor the '667 Patents had any valid exclusionary reach because the '995 Patent was invalid due to fraud upon the PTO, the '667 Patent was invalid because it would have never issued absent the underlying fraud, and the

reissuance proceedings were successful only due to Ranbaxy's anticompetitive agreement to cease protesting the reissuance.

323. Further, the Agreement exceeds the scope of the patents *even if they were valid* because the Agreement excluded generic competition from June 28, 2011 to November 30, 2011, over five months beyond the expiration of the '995 Patent and over twenty months beyond the expiration of the '893 Patent. Simply put, there was no patent protection—not even fraudulently-obtained protection—for brand name Lipitor from June 28, 2011 to November 30, 2011.

324. Pfizer's former Chairman and CEO stated in 2005:

> There are dozens of generic drug manufacturing companies with a red circle around June 28, 2011. That's the day the patent for our anti-cholesterol medication Lipitor expires . . . Shortly thereafter a number of generic alternatives to Lipitor will be introduced and consumers will have a choice of generic tablets containing atorvastatin calcium[.]

This pre-Agreement quote shows that Pfizer was well aware that its fraudulent '995 Patent was set to expire in June of 2011, and that Pfizer had no power to exclude competition with the '995 Patent beyond that date. This quote also shows Pfizer's recognition that neither the Unasserted Formulation Patents, nor the Process Patents, nor the '156 Patent, could block the entry of generic Lipitor after June 28, 2011.

325. In summary, the Agreement was unlawful for at least the following reasons: (a) it constituted an illegal market allocation agreement, pursuant to which Pfizer paid substantial monies to its competitor, Ranbaxy, in exchange for Ranbaxy's agreement to allocate the entire United States market for atorvastatin calcium to Pfizer through November 30, 2011; (b) it restricted competition in a manner, and to an extent, that exceeds the exclusionary power and potential of Pfizer's Lipitor patents; and (c) to the extent it purported to settle patent claims

against Ranbaxy for infringement of any Lipitor-related patent extending past March 24, 2010, it was baseless sham litigation that Pfizer and Ranbaxy knew had no realistic chance of prevailing on the merits.

326. There is and was no cognizable, non-pretextual procompetitive justification for the Agreement, and/or for the compensation flowing to Ranbaxy under the Agreement. Even if there were some conceivable justification, the Agreement, and the compensation flowing to Ranbaxy under the Agreement, were not reasonably necessary to achieve it.

327. Upon the expiration of the '893 Patent, Ranbaxy would have been able to enter with its generic product notwithstanding any later-expiring patent held by Pfizer. Ranbaxy would have done so immediately upon FDA approval. Ranbaxy has expressed its willingness to enter at risk with a generic product of other blockbuster drugs, telling one court that "Ranbaxy [] presently intends to manufacture, use, sell and offer to sell drug products for which the ANDA has been submitted once the FDA approves the ANDA"—in other words, Ranbaxy would launch its generic "once the FDA approv[ed]" it and would not need to await final resolution of the patent case.

I. Pfizer Thwarts Other ANDA Filers from Triggering Ranbaxy's 180-Day First-to-File Marketing Exclusivity, In Furtherance of the Agreement

328. The Agreement sought to prevent other ANDA filers from launching their own generic versions of Lipitor before Ranbaxy launched its generic on November 30, 2011. As the first filer of a generic Lipitor ANDA, Ranbaxy had 180-day marketing exclusivity, and only Ranbaxy's own first commercial marketing of the generic drug product could trigger the 180-day period. Ranbaxy's 180-day exclusivity would also commence, even if Ranbaxy had not yet begun commercial marketing, if another ANDA filer were to obtain a court decision (from which no appeal except to the Supreme Court could be taken) finding non-infringement or invalidity of

the relevant patents. Finally, Ranbaxy could lose its 180-day exclusivity if another ANDA filer convinced the FDA to deprive Ranbaxy of the exclusivity award.

329. The scenarios under which Ranbaxy's period of marketing exclusivity would commence were important to Pfizer and Ranbaxy because the possibility of other generic entrants threatened their conspiracy to allocate the market for atorvastatin calcium. Ranbaxy did not want any involuntary triggering or forfeiture of its anticipated, and enormously valuable, marketing exclusivity, and Pfizer did not want generic Lipitor competition in advance of November 30, 2011 (the date on which Ranbaxy could enter the market pursuant to the Agreement). Such events would threaten to diminish or eliminate the value of the market allocation and frustrate the Agreement. As a result, both Pfizer and Ranbaxy had a significant interest in ensuring that Ranbaxy's 180-day exclusivity was protected and in delaying the market entry of other ANDA applicants for generic Lipitor.

330. During the time of the Agreement, Pfizer was also in possession of the Unasserted Formulation Patents related to atorvastatin calcium (the '971 and '104 Patents), and one patent, the '156 patent, which covered crystalline forms of atorvastatin, all of which were listed in the Orange Book. None of these patents allowed Pfizer to exclude Ranbaxy or any other ANDA filer from the market. Pfizer avoided placing the Unasserted Formulation Patents at issue in its infringement litigation because, upon information and belief, it knew that there was no merit to such infringement claims and that it would therefore lose any such challenges. Further, affirmatively placing these patents at issue would have provided an avenue for other generic manufacturers to trigger Ranbaxy's 180-day exclusivity by securing a finding as to the invalidity or non-infringement of all of the Lipitor patents listed in the Orange Book.

331. Pursuant to and in furtherance of the Agreement, Pfizer engaged in a sustained campaign of serial meritless litigation to thwart the efforts of generic manufacturers to obtain judgments of invalidity and/or non-infringement with respect to the Lipitor patents, thus preventing the involuntary triggering of Ranbaxy's 180-day first-to-file marketing exclusivity prior to November 30, 2011.

332. In order to ensure that this campaign was successful, Pfizer settled cases prior to judgments on the merits, vigorously opposed the efforts of ANDA applicants to obtain declarations that the Unasserted Formulation Patents were invalid and/or not infringed, and otherwise engaged in a pattern of dilatory conduct designed to forestall judicial decisions that the Lipitor Patents were invalid and/or not infringed.

1. Apotex

333. For example, in December 2008, after it received a Paragraph IV certification from Apotex, Inc. and Apotex Corporation ("Apotex") as to the '995 Patent, the Unasserted Formulation Patents, and the '156 Patent, Pfizer sued Apotex only for infringement of the '995 Patent. Nonetheless, Apotex's answer included counterclaims, pursuant to 21 U.S.C. § 355(j)(5)(C), asserting non-infringement and invalidity of the both the '995 Patent (and '667 reissue Patent), the Unasserted Formulation Patents, and the '156 Patent.

334. The Apotex trial court acknowledged that "Apotex's hope is to obtain a decision from this Court that the Unasserted Patents are invalid or are not infringed by Apotex's product, thereby triggering Ranbaxy's exclusivity period. Absent such a court ruling (either in this case or in litigation involving another subsequent ANDA filer), Apotex will not be able to market its generic atorvastatin drug until 180 days after Ranbaxy begins marketing its drug, which, as a result of the settlement agreement between Pfizer and Ranbaxy, will not occur until November 2011 at the earliest."

335. In furtherance of the Agreement, Pfizer moved for dismissal of Apotex's counterclaims, arguing that they were nonjusticiable.

336. The Apotex court denied Pfizer's motion to dismiss, but Pfizer managed to delay discovery and litigation for well over a year. The delay had its intended effect; the more time that passed, and the closer it came to Ranbaxy's November 30, 2011 release date, the less the litigation was worth to Apotex, as the early trigger of Ranbaxy's 180-day exclusivity became less and less economically advantageous. The parties settled on February 27, 2012, and their joint motion to dismiss was granted on March 1, 2012.

2. Mylan

337. On May 1, 2009, Mylan sent Pfizer a letter providing notice of Mylan's ANDA submission and intent to market a generic version of Lipitor, and supplying a Paragraph IV certification as to the Unasserted Formulation Patents and the '156 Patent. In addition, Mylan offered confidential access to certain portions of Mylan's ANDA. Pfizer subsequently filed an action against Mylan on June 15, 2009, alleging infringement only of the '156 Patent and seeking a declaratory judgment for infringement of the Process Patents.

338. Mylan filed a motion for leave to file an amended answer containing counterclaims pertaining to the Unasserted Formulation Patents and seeking a declaration of noninfringement and/or invalidity with respect to the patents. Mylan sought discovery regarding the Unasserted Formulation Patents in support of that effort. On August 25, 2010, Mylan's motion to compel discovery was granted by court order.

339. Nonetheless, Pfizer continued to refuse to provide Mylan with the discovery it required. As a result, Mylan had no choice but to file an emergency motion seeking to enforce the court's discovery order.

340. On August 30, 2010, in an attempt to sabotage Mylan's continued efforts to obtain discovery and thus proceed with its counterclaims relating to the Unasserted Formulation Patents, Pfizer hastily covenanted not to sue Mylan on those patents. Pfizer did so hoping to moot Mylan's continued efforts to discover facts that would support its counterclaims and the court's order of August 25, 2010 compelling such discovery.

341. In turn, the court enforced its order requiring Pfizer to supply discovery pertaining to the Unasserted Formulation Patents. In doing so, the court expressed frustration with Pfizer's litigation tactics regarding the Unasserted Formulation Patents:

> I'm granting Mylan's request. I'm very troubled by the conduct of Pfizer here with respect to this ongoing discovery dispute. The way I see it, if Pfizer wanted to provide a covenant not to sue, it was within its authority at any time to provide the covenant not to sue with respect to the formulation patents. For whatever reasoning only known to Pfizer, they waited until August 30th [2010] to give the covenants not to sue, which was perhaps not coincidently shortly after the issuance of the August 25th order granting the defendants' request for discovery * * * That's simply just not how this is supposed to work.

342. Despite this admonition, Pfizer continued to delay the progress of the case. In a November 20, 2009 letter to the court regarding the request of Dr. Reddy's Laboratories Ltd. ("DRL") to be heard at the Markman hearing pertaining to the '156 Patent that was being held in the Mylan patent litigation, counsel for Mylan complained about Pfizer's continued efforts to delay the litigation: "Pfizer uses DRL's request to be heard on the '156 patent as another opportunity to attempt to delay the Pfizer-Mylan cases." In or around January 2011, the parties settled the litigation.

343. By way of a separate action against the FDA, Mylan sought to force a waiver of Ranbaxy's 180-day exclusivity period. Mylan's injunctive effort was rejected on standing grounds by the District Court for the District of Columbia on May 2, 2011.

3. Actavis

344. Pfizer sued Actavis Group hf, Actavis Inc., Actavis Elizabeth LLC and Actavis Pharma Manufacturing Private Ltd. (collectively "Actavis"), in August 2010, after Actavis submitted to the FDA an ANDA seeking approval to market generic Lipitor. Pfizer sued Actavis only for infringement of the '156 Patent, even though Actavis had included the Unasserted Formulation Patents in its Paragraph IV certification.

345. Actavis counterclaimed for declaratory judgment of invalidity and non-infringement of the Unasserted Formulation Patents in September 2010. In response, Pfizer moved to dismiss these counterclaims as unripe. In its opposition brief, Actavis argued that "Pfizer's listing of the [Unasserted Formulation Patents] in the Orange Book and its refusal to litigate them creates patent uncertainty and indefinitely delays the approval of Actavis' ANDA," and noted that "[e]ven if Pfizer granted Actavis a covenant not to sue on the [Unasserted Formulation Patents], however, it would not address the fact that Actavis is suffering from an indefinite delay in FDA approval of its ANDA and its concurrent inability to enter the market."

346. Actavis also argued that it "is being restrained from the free exploitation of non-infringing goods [and] suffering exactly the type of injury-in-fact that is sufficient to establish Article III standing" by virtue of Pfizer's Agreement with Ranbaxy and its refusal to litigate the validity and infringement of its Unasserted Formulation Patents. (Internal citations and quotations omitted). The parties settled the litigation on or around October 12, 2011.

347. Despite their efforts to do so, no ANDA filer was able to circumvent the Agreement between Pfizer and Ranbaxy by triggering Ranbaxy's 180-day marketing exclusivity prior to November 30, 2011.

J. Ranbaxy's ANDA Would Have Been Approved Earlier Absent Defendants' Anticompetitive Scheme

348. Ranbaxy's atorvastatin calcium ANDA would have received final approval earlier absent the Defendants' anticompetitive conduct. The FDA has policies and procedures in place to prioritize the review of ANDAs, *e.g.*, expediting the review of the first applications for which there are no blocking patents or exclusivities. Regarding the FDA's review of applications for generic Lipitor, the Agreement blocked the applicants, including Ranbaxy, from marketing their products. The FDA was aware that the earliest date Ranbaxy could market generic Lipitor under its Agreement with Pfizer was November 30, 2011. As Ranbaxy maintained the 180-day exclusivity, all subsequent applicants were blocked from marketing generic Lipitor as well, until Ranbaxy's exclusivity was triggered and had elapsed.

349. Furthermore, the FDA was under tremendous pressure, including from Congress, to speed consumer access to generic Lipitor at the earliest possible moment. This shows that the FDA would have approved Ranbaxy's ANDA earlier absent the agreed-to date for Ranbaxy's market entry contained in the Agreement.

350. Ranbaxy was also under tremendous pressure to monetize its biggest asset, *i.e.*, its first-to-file ("FTF") atorvastatin ANDA, at the earliest possible moment, so much so that Ranbaxy paid Teva a large amount of money—in effect an insurance policy—in order to, on information and belief, ensure that Ranbaxy was able to launch generic Lipitor at the earliest possible moment. This shows that Ranbaxy would have more rapidly pursued its atorvastatin calcium ANDA absent the agreed-to date for Ranbaxy's market entry contained in the Agreement.

351. On information and belief, negotiations between Ranbaxy and Teva regarding generic Lipitor began in 2009. Ranbaxy and Teva negotiated three possible ways of monetizing

Ranbaxy's first-to-file ANDA: (1) a manufacturing site transfer from Ranbaxy's facility in India to Teva, under which Teva would pay Ranbaxy a lump sum transfer fee and royalties on sales of generic Lipitor; (2) Ranbaxy and Teva both launch generic Lipitor; and (3) Ranbaxy successfully effectuates the manufacturing site transfer from India to the Ohm facility in New Jersey, pays Teva back the lump sum transfer fee, and Teva shares a portion of Ranbaxy's profits for generic Lipitor.

352. In order to capitalize on the first-to-file opportunity, Ranbaxy took steps to ensure issues related its good manufacturing practices did not prevent it from being able to market generic Lipitor. For instance, on information and belief, in December 2009 Ranbaxy effectuated a manufacturing site transfer of atorvastatin calcium from its facility in India to Ranbaxy's wholly-owned subsidiary, Ohm Laboratories, in New Jersey. Thus, whatever issues Ranbaxy may have been having with FDA regulatory compliance at one or more of its facilities in India did not affect the Ohm facility in New Jersey. This is borne out by the fact that Ranbaxy ultimately received approval to market generic Lipitor in the United States from the Ohm facility in New Jersey.

353. At or around the same time Ranbaxy filed its ANDA for atorvastatin calcium, Ranbaxy also filed the first ANDA to market a strength of simvastatin, a drug in the same "statin" family as atorvastatin calcium. On information and belief, as with atorvastatin, Ranbaxy effectuated a manufacturing site transfer for simvastatin from India to the Ohm facility in New Jersey. Ranbaxy received final approval for its simvastatin ANDA on June 23, 2006 and began marketing its first-to-file generic shortly thereafter.

354. Since Ranbaxy gained approval to market generic Lipitor from its Ohm facility in New Jersey, on information and belief, it never needed the insurance policy that the deal with

Teva effectively provided. However, Ranbaxy still paid Teva a substantial amount of money in order to be able to monetize its first-to-file atorvastatin calcium ANDA at the earliest possible moment under the Agreement

355. Ranbaxy was granted final approval on November 30, 2011, *i.e.*, simultaneously with the earliest possible moment that Ranbaxy could market generic Lipitor under the Agreement with Pfizer. Ranbaxy launched generic Lipitor in advance of that date, under "quarantine" agreements with wholesalers. If, under the Agreement (or absent the Agreement), generic Lipitor could have been marketed earlier than November 30, 2011, the FDA would have granted final approval earlier and Ranbaxy would have launched earlier.

356. The FDA did not issue its formal written denial of Pfizer's Petition until November 30, 2011 for the same reason: the FDA knew from Ranbaxy that the Agreement prevented Ranbaxy from coming onto the market until November 30, 2011. Thus, there was no need for the FDA to issue the formal written denial of Pfizer's Petition earlier than November 30, 2011, and it was for that reason that the FDA did not do so.

K. The PTO's Reissuance of the '995 Patent Does Not Absolve Warner-Lambert's Fraud or Otherwise Sanitize the '995 Patent

357. As alleged above, but for Warner-Lambert's fraud on the PTO during the initial prosecution of the '995 Patent, the '995 Patent never would have issued. But for the '995 Patent's additional period of patent protection, at least one generic version of Lipitor would have been available far earlier than it was.

358. That Pfizer later went back and sought reissuance of the '995 Patent to correct a technical defect in one of its claims—claims that were found patentable in the first instance only because of Warner-Lambert's fraudulent assertion that the R-trans enantiomer was ten times more active than the racemate—does not change the fact that the '995 Patent would have never

issued initially but for Warner-Lambert's fraud. And without the *original issuance* of the '995 Patent, there could be no *reissuance* of it. Without the reissue proceedings, the reissue patent that did emerge from that proceeding, the '667 Patent, would not exist. As a result, the PTO's eventual decision to reissue the '995 Patent is immaterial to this action.

359. Instead, the reissuance proceedings simply confirm what Warner-Lambert had long known: the biologic data submitted as part of the application for the '995 Enantiomer Patent was false, inaccurate, and riddled with errors. Throughout the reissuance proceedings, Pfizer itself eschewed all reliance on biologic data (including CSI data), at one point explicitly acknowledging that the biologic data originally used to support patentability was "inaccurate."

360. Rather than submit "corrected" biologic data, Pfizer took an entirely new tact: Pfizer argued that Lipitor is entitled to additional protection under the '995 Patent because of Lipitor's overwhelming commercial success. But Pfizer's commercial success argument is no more viable as support for reissuance of the '995 Enantiomer Patent than Warner-Lambert's "surprising activity" argument was during the initial application process.

1. Pfizer Admits that the Biologic Data is False

361. In January 2007, in the wake of the Federal Circuit decision invalidating on technical grounds Claim 6 of the '995 Enantiomer Patent, Pfizer sought re-issuance of the '995 Patent "to correct a technical defect in some of the patent claims."

362. Pfizer knew, as a result of international patent litigation, that it could no longer rely publicly on the falsified biologic data that Warner-Lambert had submitted to the PTO during its prosecution of the '995 Patent, conducted from 1989 to 1993. As a result, during the reissuance proceedings, Pfizer expressly disavowed reliance on that biologic data, including the data presented in the CSI Table and Roth Declaration.

363. Roth and Pfizer submitted the Claim 6 '995 Patent reissue application on January 16, 2007. The applicants did not amend or modify the '995 Patent specification as part of the reissuance proceedings. Roth's remarks include a list of the "objective evidence" that "completely refutes any suggestion of obviousness." Notably, this list does *not* include the purported surprising effectiveness of the R-trans enantiomer or the alleged ten times greater activity of the R-trans enantiomer as compared to the racemate.

364. Moreover, Pfizer's Informational Disclosure Statement eschewed reliance on CSI and COR biologic data:

> Subsequent to the Federal Circuit's decision, while preparing for trial in Australia on a '995 counterpart, Pfizer first learned of significant errors in the COR results which neither Pfizer nor the parties adverse to it had discovered before. This discovery led Pfizer to advise the Federal Circuit that COR data could not be relied on to compare the relative activity of compounds – see Exhibit 9, page 10, fn 2. Thus any earlier reference in Pfizer's findings, conclusions and brief to relative activity among compounds based on the COR test is withdrawn and is not relied on in these reissue proceedings. *Pfizer does not at this point in the reissue rely for patentability on any comparisons based on CSI.* Neither CSI no COR data were relied on by either U.S. court in reaching their decisions regarding the validity of '995 claim 6."

(Emphasis added). Pfizer similarly stated, "Pfizer does not now rely on any . . . data [comparing between and among calcium salts and other salts of atorvastatin and its racemates] in support of patentability."

365. In May 2007, Ranbaxy filed a protest with the PTO against Pfizer's reissue application. Ranbaxy would continue protesting the reissue application for about another year until, pursuant to the Agreement, Ranbaxy discontinued doing so.

366. On June 7, 2007, Pfizer submitted a Second Informational Disclosure Statement that discussed "Foreign Proceedings on '995 Counterparts" and attached additional materials produced as part of certain non-U.S. proceedings. Pfizer acknowledged therein that the biologic

data submitted in support of its patent applications—the CSI Table, the Roth Declaration, and the foreign "'995 counterparts"— was inaccurate:

> [A]pplicant is submitting these documents to permit the Examiner to consider their potential materiality. Further, many of these documents … contain biological data or summaries of biological date, and *some of that biological data is now understood to be inaccurate* (due to transcription errors, calculation errors, experimental errors, etc.). Applicant is not submitting *corrected* biological data at the present time because, as applicant has emphasized repeatedly in these reissue proceedings, applicant is not currently relying on the biological data for patentability.

(Emphasis added).

367. Elsewhere in the reissuance proceedings, Roth and Pfizer referred to the biological data at issue in the Australian and Canadian patent litigation as "biologic data that Pfizer *then* argued showed that the atorvastatin enantiomer had unexpected and surprising inhibition of cholesterol biosynthesis in-vitro in comparison to the racemic form of atorvastatin," while reiterating that they "are *not* relying on any of the biological data as a basis for the patentability of the pending claims at the present time." (Emphasis added). Similarly, Roth and Pfizer stated that the "[a]pplicant is not submitting *corrected* biological data at the present time because, as applicant has emphasized repeatedly in these reissue proceedings, applicant is not currently relying on the biological data for patentability." (Emphasis added).

368. Despite this express disavowal of the biological data, at one point during the reissuance proceedings, the Examiner relied on the biological data to overcome an obviousness rejection:

> Claims 6, 13 and 14 have not been rejected as being obvious as the declaration of Bruce D. Roth filed February 25, 1991 discloses unexpected properties which would overcome any 35 USC 103(a) rejection of claims 6, 13 and 14 as *atorvastatin calcium was shown to have activity greater than fifty-fold more than that of the S-trans and at least ten-fold more than that of the racemate.*

(Emphasis added).

369. In response to this error, Pfizer reiterated that it was "not presently relying on any of the biological data (including the data contained in the Roth Declaration) as support for the patentability of claims 6, 13 and 14." Pfizer acknowledged that the Examiner had relied on the Roth Declaration and asked her to "withdraw her reliance on the data in the Roth Declaration" and to focus on Pfizer's new argument: that it was entitled to additional patent protection based on Lipitor's commercial success.

370. On April 24, 2008, the PTO issued a non-final rejection of claims 6, 13, and 14. In doing so, the Examiner formally withdrew her reliance on the Roth Declaration. Instead, the Examiner relied on secondary considerations raised and identified by the Applicants, namely Lipitor's commercial success.

371. On April 6, 2009, the PTO reissued claims 6, 13, and 14 of the '995 Patent as the '667 Patent. As previously discussed, the reissued patent retained the same expiration date.

2. Lipitor's Commercial Success Has No Bearing on Whether the Invention Claimed by the '995 Patent is Obvious

372. The PTO based its ruling to grant the reissuance of the '995 Enantiomer Patent not on the basis of the biological studies and the associated representations made by Warner-Lambert (even though a version of the CSI assay data remains in the specification for the patent), but instead on Pfizer's arguments that the commercial success of Lipitor shows that the '995 Enantiomer Patent could not have been obvious. This argument is patently wrong as a matter of fact and law.

373. First, Lipitor was commercially successful during the 1997-2010 time period, a period during which it enjoyed patent protection under both the '893 Original Lipitor Patent and the '995 Enantiomer Patent. Since the relevant question of obviousness is whether the '995

Patent is obvious when compared to the '893 Patent, the fact that Lipitor, which is covered by both patents, has been commercially successful generally provides no meaningful information as to the distinctions *between* the two patents.

374. Second, when Pfizer boasts of Lipitor's "commercial success," it makes comparisons between Lipitor and other statins, or between Lipitor and the overall growth in the statin market generally. But the relevant issue of obviousness does not involve a comparison of Lipitor to other statins or to growing statin use. Instead, the relevant issue of patent obviousness is whether the invention under the '995 Enantiomer Patent would have been successful as compared to an invention under the '893 Original Lipitor Patent. However, because both the '893 and '995 Patents cover the same product, looking to Lipitor's general success, or to its success as compared to other statins, provides no insight as to whether the '995 Patent is obvious as compared to the earlier '893 Patent. To have any kind of a meaningful "commercial success" information as it relates to whether the '995 Enantiomer Patent was obvious, one must compare an invention under the '995 Patent to a *different* invention under the '893 Patent. There is no invention that fulfills these parameters.

375. Pfizer knew that this argument of looking generally at "Lipitor" (rather than distinguishing attributes of the enantiomer that were surprising and unexpected) was a deception. Pfizer knew that the '893 Patent protected Lipitor from the initial launch of Lipitor through all of the re-issue proceedings. Thus, any showing of success of Lipitor generally would not in any way elucidate why the '995 Patent (which *also* covered Lipitor) was not obvious over the original '893 compound patent. Indeed, Warner-Lambert, and later Pfizer, repeatedly used the '893 Patent as the patent which would provide protection for Lipitor. Warner-Lambert listed the

'893 Patent in the Orange Book, thus protecting Lipitor from generic competition.[19] Shortly after Lipitor was approved by the FDA in late 1996, Warner-Lambert sought, and obtained, a patent extension on the '893 Patent (not the '995 Patent) to make up for the many years that it took to study Lipitor. And Pfizer later brought infringement cases against generic companies arguing that their proposed Lipitor products would infringe the '893 Patent.

376. Put simply, from late 1996 to 2009, Pfizer's commercialization of Lipitor was actively protected by both the original '893 Patent and the '995 Patent, *i.e.*, both patents covered, the commercialized R-trans enantiomer calcium salt formulation. Thus, any arguments raised with the PTO at any time regarding the commercial success of "Lipitor" could not, as a matter of fact or law, elucidate in any way whatsoever whether the '995 Patent was non-obvious over the '893 Patent.[20]

377. In summary, Pfizer and its predecessors obtained, by actual fraud, the '995 Enantiomer Patent. If Pfizer and its predecessors had not committed actual fraud during the prosecution of the '995 Patent, the PTO would not have issued the '995 Enantiomer Patent and there would not have been any commercial success attributable to the '995 Patent (or other argument as to the validity thereof) on which the Examiner could have relied to reissue the '995 Patent.

378. Without the '995 Patent, generic manufacturers, many of which filed their ANDAs years ago, would have entered the market far earlier than they did.

[19] The use code used for the '893 Patent to cover Lipitor was a "method of inhibiting cholesterol biosynthesis in a patient." Similarly, the use code used for the '995 Patent was defined as a "method of use to inhibit cholesterol synthesis in a human suffering from hypercholesterolemia."

[20] Notably, Pfizer's re-issue application stated that the re-wording of the '995 Patent should be allowed so that the "active ingredient responsible for Lipitor's success [could] be restored and the active ingredient that makes Lipitor work will again be protected by species claims," falsely suggesting that without the allowance Lipitor would be without patent protection. This was a false suggestion because Lipitor's active ingredient was also covered by the original '893 patent as well.

VI. EFFECT ON INTERSTATE COMMERCE

379. Defendants' conduct in unlawfully monopolizing and restraining trade and competition in the market for atorvastatin calcium has substantially affected interstate and foreign commerce.

380. During the relevant time period, Pfizer manufactured, promoted, distributed, and sold substantial amounts of branded Lipitor in a continuous and uninterrupted flow of commerce across state and national lines and throughout the United States. Beginning around November 30, 2011, Ranbaxy did the same with respect to generic Lipitor.

381. During the relevant time period, Pfizer transmitted funds as well as contracts, invoices, and other forms of business communications and transactions in a continuous and uninterrupted flow of commerce across state and national lines in connection with the sale of branded Lipitor. Beginning around November 30, 2011, Ranbaxy did the same with respect to generic Lipitor.

382. In furtherance of their successful efforts to monopolize and restrain competition in the market for atorvastatin calcium, Defendants employed the United States mail and interstate and international telephone lines, as well as means of interstate and international travel. The activities of Defendants were within the flow of and have substantially affected interstate commerce.

VII. EFFECT ON INTRASTATE COMMERCE

383. During the relevant time period, branded Lipitor, manufactured and sold by Pfizer, was shipped into each state and was sold to or paid for by end payors. Beginning around November 30, 2011, generic Lipitor, manufactured and sold by Ranbaxy, was shipped into each state and was sold to or paid for by end payors.

384. During the relevant time period, in connection with the purchase and sale of branded Lipitor, money and business communications and transactions occurred in each state. Beginning around November 30, 2011, in connection with the purchase and sale of generic Lipitor, money and business communications and transactions occurred in each state.

385. Defendants' conduct as set forth in this Complaint had substantial effects on intrastate commerce in each state because Lipitor was sold to consumers and third-party payors in each state and Defendants entered into an unlawful anticompetitive agreement that affected commerce in each state.

VIII. MONOPOLY POWER AND MARKET DEFINITION

386. At all relevant times, Pfizer had nationwide monopoly power, including in each of the United States, the District of Columbia, and the Commonwealth of Puerto Rico, because it had the power to maintain the price of the drug of Lipitor at supracompetitive levels without losing substantial sales to other products prescribed and/or used for the same purposes as Lipitor, with the exception of AB-rated generic versions of Lipitor.

387. A small but significant, non-transitory price increase for Lipitor by Pfizer would not have caused a significant loss of sales to other products prescribed and/or used for the same purposes as Lipitor, with the exception of AB-rated generic versions of Lipitor.

388. Lipitor does not exhibit significant, positive cross-elasticity of demand with respect to price with any product other than AB-rated generic versions of Lipitor.

389. Because of, among other reasons, its use and varying ability to inhibit the production of cholesterol, Lipitor is differentiated from all products other than AB-rated generic versions of Lipitor.

390. Defendants needed to control only Lipitor and its AB-rated generic equivalents, and no other products, in order to maintain the price of Lipitor profitably at supracompetitive

prices. Only the market entry of a competing, AB-rated generic version of Lipitor would render Pfizer unable to profitably maintain its current prices of Lipitor without losing substantial sales.

391. Pfizer also sold Lipitor at prices well in excess of marginal costs, and in excess of the competitive price, and enjoyed high profit margins.

392. Defendants have had, and exercised, the power to exclude and restrict competition to Lipitor and AB-rated bioequivalents.

393. To the extent that Plaintiffs are legally required to prove monopoly power circumstantially by first defining a relevant product market, Plaintiffs allege that the relevant market is atorvastatin calcium products – *i.e.*, Lipitor (in all its forms and dosage strengths) and AB-rated bioequivalent atorvastatin calcium products. During the period relevant to this case, Defendants have been able to profitably maintain the price of Lipitor and/or AB-rated bioequivalents well above competitive levels.

394. Defendants, at all relevant times, enjoyed high barriers to entry with respect to competition to the above-defined relevant product market due to patent and other regulatory protections and high costs of entry and expansion.

395. The relevant geographic market is the United States and its territories.

396. Pfizer's market share in the relevant market was 100% until November 30, 2011, implying a substantial amount of monopoly power.

IX. MARKET EFFECTS

397. On or shortly before November 29, 2011, prior to receiving the FDA's formal, written final approval of its ANDA, Ranbaxy began to ship generic Lipitor. However, Ranbaxy stated that the shipments of generic Lipitor were subject to "quarantine." In other words, until Ranbaxy received the FDA's formal, written final approval of its ANDA, generic Lipitor could not be resold to Plaintiffs and members of the Class.

398. By practice, the FDA organizes its priorities around "rate limiters." The FDA knew that the Agreement between Pfizer and Ranbaxy prevented Ranbaxy from selling generic Lipitor until November 30, 2011. The agreement was thus a rate limiter. Accordingly, the FDA purposely waited to issue formal written denial of Pfizer's citizen petition and to issue formal written approval of Ranbaxy's ANDA until November 30, 2011, even though the ANDA was in an approvable condition well before November 30, 2011 and, if not for the Agreement, would have received final FDA approval at an earlier time.

399. Defendants' acts and practices had the purpose and effect of restraining competition unreasonably and injuring competition by protecting Lipitor from generic competition. Defendants' actions allowed Pfizer to maintain a monopoly and to exclude competition in the market for Lipitor and its AB-rated generic equivalents, to the detriment of Plaintiffs and all other members of the End-Payor Class.

400. Defendants' exclusionary conduct has delayed generic competition and unlawfully enabled Pfizer to sell Lipitor without generic competition. But for Defendants' illegal conduct, one or more generic competitors would have begun marketing AB-rated generic versions of Lipitor earlier than November 30, 2011, the date on which Ranbaxy first marketed its generic version of the drug. A generic Lipitor would have been on the market much sooner.

401. Pfizer entered into agreements with Medco Health Solutions and several of the nation's largest pharmacy benefit managers whereby the price of brand name Lipitor would—and did—effectively decrease upon the entrance of generic competition.

402. Pfizer, acting alone and/or in concert with Ranbaxy, willfully and unlawfully maintained its monopoly power and unlawfully conspired in restraint of trade by engaging in an overarching scheme to exclude competition that discouraged, rather than encouraged,

competition on the merits. This scheme was designed for the anticompetitive purpose of forestalling generic competition and was carried out with the anticompetitive effect of maintaining supracompetitive prices for the relevant product. Pfizer implemented its scheme by, *inter alia*, manipulating the prosecution of the '995 Patent, manipulating the reissuance process for the '995 Patent, prosecuting serial sham patent infringement litigation, filing a sham citizen petition, settling on terms outside the scope of the patent to divide and allocate markets, entering into anticompetitive reverse payment agreements without necessary procompetitive justifications, and abusing the Hatch-Waxman framework, in concert with Ranbaxy, to serve its anticompetitive goals.

403. The generic manufacturers seeking to sell generic Lipitor had extensive experience, capability, and expertise in the pharmaceutical industry, including in obtaining approval for ANDAs and marketing generic pharmaceutical products. These generic manufacturers had taken affirmative steps to enter the market, including, without limitation, filing ANDAs with the FDA, and they were otherwise prepared and planned to enter the market.

404. Defendants' illegal acts, which delayed introduction into the U.S. marketplace of generic versions of Lipitor, have caused Plaintiffs and the Class to pay more than they would have paid for atorvastatin calcium products absent Defendants' illegal conduct.

405. Typically, generic versions of brand-name drugs are initially priced significantly below the corresponding reference listed drug ("RLD") branded counterpart to which they are AB-rated. As a result, upon generic entry, end-payors rapidly substitute generic versions of the drug for some or all of their purchases. As more generic manufacturers enter the market, prices for generic versions of a drug predictably plunge even further due to competition among the generic manufacturers, and, correspondingly, the brand name drug loses even more of its market

share to the generic versions of the drug. This price competition enables all purchasers of the drugs to: (a) purchase generic versions of a drug at substantially lower prices, and/or (b) purchase the brand name drug at a reduced price. Consequently, brand name drug manufacturers have a keen financial interest in delaying the onset of generic competition, and purchasers experience substantial cost inflation from that delay.

406. If generic competitors had not been unlawfully prevented from earlier entering the market and competing with Defendants, end-payors, such as Plaintiffs and members of the Class, would have paid less for atorvastatin calcium by (a) substituting purchases of less-expensive AB-rated generic Lipitor for their purchases of more-expensive branded Lipitor, (b) receiving discounts on their remaining branded Lipitor purchases, and (c) purchasing generic Lipitor at lower prices sooner.

407. Defendants' unlawful conduct had substantial and significant intrastate effects in each state because, *inter alia*, Lipitor and AB-rated generic Lipitor were sold to consumers and third-party payors in each state at higher prices than would have existed absent the unlawful conduct, and Defendants entered into an unlawful agreement that affected commerce, product availability, and competition in each state.

408. Moreover, due to Defendants' conduct, other generic manufacturers were discouraged from and/or delayed in developing generic versions of Lipitor.

409. Thus, Defendants' unlawful conduct deprived Plaintiffs and the Class of the benefits of competition that the antitrust laws were designed to ensure.

X. ANTITRUST IMPACT

410. During the relevant period, Plaintiffs and members of the Class purchased substantial amounts of Lipitor indirectly from Defendants and/or purchased substantial amounts of AB-rated Lipitor bioequivalent generics indirectly from Defendants or others. As a result of

Defendants' illegal conduct, members of the End-Payor Class were compelled to pay, and did pay, artificially inflated price for their atorvastatin calcium requirements. Those prices were substantially greater than the prices that members of the Class would have paid absent the illegal conduct alleged herein, because: (1) the price of brand-name Lipitor was artificially inflated by Defendants' illegal conduct, (2) Class members were deprived of the opportunity to purchase lower-priced generic versions of Lipitor sooner, and/or (3) the price of AB-rated Lipitor generic atorvastatin calcium was artificially inflated by Defendants' illegal conduct.

411. As a consequence, Plaintiffs and members of the Class have sustained substantial losses and damage to their business and property in the form of overcharges. The full amount and forms and components of such damages will be calculated after discovery and upon proof at trial. Commonly used and well-accepted economic models can be used to measure both the extent and the amount of the supracompetitive charge passed through the chain of distribution to end payors such as Plaintiffs and members of the Class.

412. General economic theory recognizes that any overcharge at a higher level of distribution generally results in higher prices at every level below. *See* Hovenkamp, FEDERAL ANTITRUST POLICY, THE LAW OF COMPETITION AND ITS PRACTICE (1994) at 624. According to Professor Hovenkamp, "[e]very person at every stage in the chain will be poorer as a result of the monopoly price at the top." Professor Hovenkamp also acknowledges that "[t]heoretically, one can calculate the percentage of any overcharge that a firm at one distribution level will pass on to those at the next level."

413. Further, the institutional structure of pricing and regulation in the pharmaceutical drug industry assures that overcharges at the higher level of distribution are passed on to indirect

purchasers. Wholesalers and retailers passed on the inflated prices of Lipitor and AB-rated generic Lipitor to Plaintiffs and the Class of end-payors defined herein.

414. Pfizer's anticompetitive actions enabled it to indirectly charge consumers and third-party payors prices in excess of what it otherwise would have been able to charge absent its unlawful actions individually and with Ranbaxy.

415. The prices were inflated as a direct and foreseeable result of Pfizer's anticompetitive conduct individually and with Ranbaxy.

416. The inflated prices the End-Payor Class paid are traceable to, and the foreseeable result of, the overcharges by Pfizer and Ranbaxy.

XI. CLASS ACTION ALLEGATIONS

417. Plaintiffs, on behalf of themselves and all End-Payor Class members, seek damages, measured as overcharges, trebled, against Defendants based on allegations of anticompetitive conduct in the market for Lipitor and its AB-rated generic equivalents.

418. Plaintiffs bring this action on behalf of themselves and, under Fed. R. Civ. P. 23(a) and (b)(3), as representatives of an End-Payor Class defined as follows:

> All persons or entities in the United States and its territories who purchased and/or paid for some or all of the purchase price for Lipitor and/or its AB-rated generic equivalents in Alabama, Arkansas, Arizona, California, Colorado, Delaware, Florida, Georgia, Hawaii, Iowa, Idaho, Illinois, Kansas, Kentucky, Louisiana, Massachusetts, Maryland, Maine, Michigan, Minnesota, Missouri, Mississippi, Montana, North Carolina, North Dakota, Nebraska, New Jersey, New Mexico, Nevada, New York, Ohio, Oklahoma, Pennsylvania, Rhode Island, South Carolina, Tennessee, Texas, Utah, Virginia, Vermont, Washington, West Virginia, and Wisconsin, in any form, for consumption by themselves, their families, or their members, employees, insureds, participants, or beneficiares (the "Class"), other than for resale, during the period March 24, 2010 through and until the anticompetitive effects of Defendants' unlawful conduct cease (the "Class Period"). For purposes of the Class

definition, persons or entities "purchased" Lipitor or its generic equivalent if they paid or reimbursed some or all of the purchase price.

419. The following persons or entities are excluded from the proposed class:

a. Defendants and their officers, directors, management, employees, subsidiaries, or affiliates;

b. All persons or entities who purchased Lipitor or its AB-rated generic equivalent for purposes of resale or directly from Defendants or their affiliates;

c. Fully insured health plans (*i.e.*, Plans that purchased insurance from another third-party payor covering 100% of the Plan's reimbursement obligations to its members);

d. State and local governments to the extent that their claims may be asserted under applicable state law only by the state Attorney General, or are otherwise prohibited by applicable law from being asserted by private counsel on a contingent fee basis;

e. The judges in this case and any members of their immediate families.

420. Members of the End-Payor Class are so numerous that joinder is impracticable. Plaintiffs believe that the Class includes hundreds of thousands, if not millions, of consumers, and thousands of third-party payors.

421. Plaintiffs' claims are typical of the claims of the members of the End-Payor Class. Plaintiffs and all members of the End-Payor Class were damaged by the same wrongful conduct of Defendants, *i.e.*, they paid artificially inflated prices for atorvastatin calcium and were deprived of the benefits of earlier and more robust competition from cheaper generic versions of Lipitor as a result of Defendants' wrongful conduct.

422. Plaintiffs will fairly and adequately protect and represent the interests of the End-Payor Class. The interests of the Plaintiffs are coincident with, and not antagonistic to, those of the End-Payor Class.

423. Plaintiffs are represented by counsel with experience in the prosecution of class action antitrust litigation, and with particular experience with class action antitrust litigation involving pharmaceutical products.

424. Questions of law and fact common to the members of the End-Payor Class predominate over questions that may affect only individual Class members because Defendants have acted on grounds generally applicable to the entire End-Payor Class, thereby making overcharge damages with respect to the End-Payor Class as a whole appropriate. Such generally applicable conduct is inherent in Defendants' wrongful conduct.

425. Questions of law and fact common to the End-Payor Class include:

a. whether Defendants willfully obtained and/or maintained monopoly power over Lipitor and its generic equivalents;

b. whether Warner-Lambert improperly listed the '995 Patent in the Orange Book;

c. whether Defendants unlawfully excluded competitors and potential competitors from the market for Lipitor and its AB-rated generic bioequivalents;

d. whether Defendants unlawfully delayed or prevented generic manufacturers from coming to market in the United States;

e. whether Defendants maintained monopoly power by delaying generic entry;

f. whether Defendants entered into an unlawful agreement in restraint of trade;

g. whether the law requires definition of a relevant market when direct proof of monopoly power is available and, if so, the definition of the relevant market;

h. whether the activities of Defendants as alleged herein have substantially affected interstate commerce;

i. whether, and to what extent, Defendants' conduct caused antitrust injury (*i.e.*, overcharges) to Plaintiffs and the members of the Class; and

j. the quantum of aggregate overcharge damages to the Class.

426. Class action treatment is a superior method for the fair and efficient adjudication of the controversy. Such treatment will permit a large number of similarly situated persons to prosecute their common claims in a single forum simultaneously, efficiently, and without the unnecessary duplication of evidence, effort, or expense that numerous individual actions would engender. The benefits of proceeding through the class mechanism, including providing injured persons or entities a method for obtaining redress on claims that could not practicably be pursued individually, substantially outweighs potential difficulties in management of this class action.

427. Plaintiffs know of no special difficulty to be encountered in the maintenance of this action that would preclude its maintenance as a class action.

XII. CLAIMS FOR RELIEF

FIRST CLAIM FOR RELIEF
For Monopolization Under State Law
(Asserted Against Pfizer)

428. Plaintiff incorporates by reference the preceding allegations.

429. As described above, from at least July 21, 1987 until November 30, 2011, Pfizer possessed monopoly power nationwide and in each of the United States, the District of Columbia, and the Commonwealth of Puerto Rico, in the market for atorvastatin calcium products. No other manufacturer sold a competing version of Lipitor before November 30, 2011.

430. Pfizer willfully and unlawfully acquired and maintained its monopoly power in the atorvastatin calcium market through at least November 30, 2011 by engaging in an anticompetitive scheme to keep generic equivalents from the market—not as a result of providing a superior product, business acumen, or historical accident.

431. Pfizer knowingly and intentionally engaged in an anticompetitive scheme to monopolize the atorvastatin calcium products (*i.e.*, Lipitor in all its forms and dosage strengths) and AB-rated bioequivalent atorvastatin calcium products market, as described above. Pfizer accomplished this scheme by, *inter alia*, (i) fraudulently obtaining the '995 Enantiomer Patent, (ii) fraudulently listing the '995 Enantiomer Patent in the Orange Book, (iii) filing serial sham infringement litigation against multiple generic manufacturers claiming infringement of the fraudulently-obtained '995 Enantiomer Patent, (iv) filing a sham citizen petition, (v) fraudulently obtaining reissuance of the '995 Patent, (vi) unlawfully agreeing with Ranbaxy to divide a market and delay price reductions for Lipitor, and (vii) otherwise engaging in an overarching scheme to unlawfully monopolize and conspire to monopolize the market for atorvastatin calcium.

432. The goal, purpose, and effect of Pfizer's scheme was to prevent and delay the sale of atorvastatin calcium products in the United States at prices significantly below Pfizer's prices for Lipitor, thereby effectively preventing the average market price of atorvastatin calcium products from declining dramatically.

433. The goal, purpose and effect of Pfizer's scheme was also to maintain and extend its monopoly power with respect to atorvastatin calcium products. Pfizer's illegal scheme allowed Pfizer to continue charging supracompetitive prices for atorvastatin calcium products, without a substantial loss of sales, reaping substantial unlawful monopoly profits.

434. Plaintiffs and members of the Class purchased substantial amounts of Lipitor and/or AB-rated generic equivalents indirectly from Pfizer and/or other manufacturers.

435. Pfizer knowingly and intentionally engaged in sham litigation against potential manufacturers of AB-rated generic equivalents of Lipitor. Pfizer repeatedly asserted that the

generic Lipitor formulations of its competitors infringed its patents, despite knowing that the Lipitor patents were fraudulently procured, invalid, non-infringed, and/or unenforceable. Pfizer filed these sham lawsuits for purposes of using a governmental process as an anticompetitive weapon to keep AB-rated generic equivalents off the market.

436. Pfizer also knowingly and intentionally engaged in a second sham litigation against Ranbaxy when it raised claims regarding the Process Patents (which had been rejected by a Delaware district court in the earlier litigation) in order to provide cover for a "settlement" agreement that extended Pfizer's atorvastatin calcium monopoly and provided for global market allocation. Pfizer knew at the time it filed the second sham lawsuit that it had no realistic likelihood of success; therefore, Pfizer knew that no reasonable pharmaceutical manufacturer in its position would have believed it had a reasonable chance of succeeding on the merits.

437. As a result of Defendants' illegal conduct, Plaintiffs and members of the Class were compelled to pay, and did pay, more than they would have paid for their atorvastatin calcium requirements absent Defendants' illegal conduct. But for Defendants' illegal conduct, competitors would have begun selling generic Lipitor sooner than they did, and prices for atorvastatin calcium products would have been lower, sooner.

438. Had manufacturers of generic atorvastatin calcium products entered the market and lawfully competed with Pfizer in a timely fashion, Plaintiffs and other members of the Class would have substituted lower-priced generic atorvastatin calcium products for the higher-priced brand-name Lipitor for some or all of their atorvastatin calcium products requirements, and/or would have paid lower net prices on their remaining Lipitor and/or AB-rated bioequivalent purchases.

439. By engaging in the foregoing conduct, Pfizer violated the following state antitrust laws:

a. Pfizer intentionally and wrongfully maintained monopoly power in the relevant market in violation of Arizona Rev. Stat. §§ 44-1403, *et seq.*, with respect to purchases of Lipitor and AB-rated bioequivalents in Arizona by members of the Class.

b. Pfizer intentionally and wrongfully maintained monopoly power in the relevant market in violation of Cal. Bus. & Prof. Code §§ 17200, *et seq.*, with respect to purchases of Lipitor and AB-rated bioequivalents in California by members of the Class.

c. Pfizer intentionally and wrongfully maintained monopoly power in the relevant market in violation of D.C. Code §§ 28-4503, *et seq.*, with respect to purchases of Lipitor and AB-rated bioequivalents in the District of Columbia by members of the Class.

d. Pfizer intentionally and wrongfully maintained monopoly power in the relevant market in violation of Fla. Stat. §§ 501.201, *et seq.*, with respect to purchases of Lipitor and AB-rated bioequivalents in Florida by members of the Class.

e. Pfizer intentionally and wrongfully maintained monopoly power in the relevant market in violation of Me. Rev. Stat. Ann. 10, §§ 1102, *et seq.*, with respect to purchases of Lipitor and AB-rated bioequivalents in Maine by members of the Class.

f. Pfizer intentionally and wrongfully maintained monopoly power in the relevant market in violation of Mass. Ann. Laws ch. 93A, *et seq.*, with respect to purchases

of Lipitor and AB-rated bioequivalents in Massachusetts by members of the Class.

g. Pfizer intentionally and wrongfully maintained monopoly power in the relevant market in violation of Mich. Comp. Laws Ann. §§ 445.773, *et seq.*, with respect to purchases of Lipitor and AB-rated bioequivalents in Michigan by members of the Class.

h. Pfizer intentionally and wrongfully maintained monopoly power in the relevant market in violation of Minn. Stat. §§ 325D.49, *et seq.*, and Minn. Stat. § 8.31, *et seq.*, with respect to purchases of Lipitor and AB-rated bioequivalents in Minnesota by members of the Class.

i. Pfizer intentionally and wrongfully maintained monopoly power in the relevant market in violation of Miss. Code Ann. §§ 75-21-3, *et seq.*, with respect to purchases of Lipitor and AB-rated bioequivalents in Mississippi by members of the Class.

j. Pfizer intentionally and wrongfully maintained monopoly power in the relevant market in violation of Neb. Code Ann. §§ 59-802, *et seq.*, with respect to purchases of Lipitor and AB-rated bioequivalents in Nebraska by members of the Class.

k. Pfizer intentionally and wrongfully maintained monopoly power in the relevant market in violation of Nev. Rev. Stat. Ann. §§ 598A.060, *et seq.*, with respect to purchases of Lipitor and AB-rated bioequivalents in Nevada by members of the Class.

l. Pfizer intentionally and wrongfully maintained monopoly power in the relevant market in violation of N.M. Stat. Ann. §§ 57-1-2, *et seq.*, with respect to purchases of Lipitor and AB-rated bioequivalents in New Mexico by members of the Class.

m. Pfizer intentionally and wrongfully maintained monopoly power in the relevant market in violation of N.C. Gen. Stat. §§ 75-2.1, *et seq.*, with respect to purchases of Lipitor and AB-rated bioequivalents in North Carolina by members of the Class.

n. Pfizer intentionally and wrongfully maintained monopoly power in the relevant market in violation of N.D. Cent. Code §§ 51-08.1-03, *et seq.*, with respect to purchases of Lipitor and AB-rated bioequivalents in North Dakota by members of the Class.

o. Pfizer intentionally and wrongfully maintained monopoly power in the relevant market in violation of 10 L.P.R.A. § 251, *et seq.*, with respect to purchases of Lipitor and AB-rated bioequivalents in Puerto Rico by members of the Class.

p. Pfizer intentionally and wrongfully maintained monopoly power in the relevant market in violation of S.D. Codified Laws §§ 37-1-3.2, *et seq.*, with respect to purchases of Lipitor and AB-rated bioequivalents in South Dakota by members of the Class.

q. Pfizer intentionally and wrongfully maintained monopoly power in the relevant market in violation of Tenn. Code Ann. §§ 47-25-101, *et seq.*, with respect to purchases of Lipitor and AB-rated bioequivalents in Tennessee by members of the Class.

r. Pfizer intentionally and wrongfully maintained monopoly power in the relevant market in violation of Vt. Stat. Ann. 9, §§ 2453, *et seq.*, with respect to purchases of Lipitor and AB-rated bioequivalents in Vermont by members of the Class.

s. Pfizer intentionally and wrongfully maintained monopoly power in the relevant markets in violation of W.Va. Code §§ 47-18-4, *et seq.*, with respect to purchases of Lipitor and AB-rated bioequivalents in West Virginia by members of the Class.

t. Pfizer intentionally and wrongfully maintained monopoly power in the relevant market in violation of Wis. Stat. §§ 133.03, *et seq.*, with respect to purchases of Lipitor and AB-rated bioequivalents in Wisconsin by members of the Class.

440. Plaintiffs and members of the Class have been injured in their business or property by reason of Defendants' antitrust violations alleged in this Claim. Their injuries consist of: (1) being denied the opportunity to purchase lower-priced generic atorvastatin calcium products, sooner, and (2) paying higher prices for atorvastatin calcium products than they would have paid in the absence of Defendants' conduct. These injuries are of the type the antitrust laws were designed to prevent, and flow from that which makes Defendants' conduct unlawful.

441. Plaintiffs and the Class seek damages and multiple damages as permitted by law for their injuries by Defendants' violations of the aforementioned statutes.

SECOND CLAIM FOR RELIEF
For Conspiracy to Monopolize Under State Law
(Asserted Against All Defendants)

442. Plaintiffs incorporate by reference the preceding allegations.

443. As described above, from at least July 21, 1987 until November 30, 2011, Pfizer possessed monopoly power nationwide and in each of the United States, the District of

Columbia, and the Commonwealth of Puerto Rico, in the market for atorvastatin calcium products. No other manufacturer sold a competing version of Lipitor before November 30, 2011.

444. Defendants willfully and unlawfully engaged in a continuing illegal conspiracy to monopolize the atorvastatin calcium market through at least November 30, 2011 by engaging in an anticompetitive scheme to keep generic equivalents from the market—not as a result of providing a superior product, business acumen, or historical accident.

445. Defendants knowingly and intentionally conspired to monopolize the atorvastatin calcium products (*i.e.*, Lipitor in all its forms and dosage strengths) and AB-rated bioequivalent atorvastatin calcium products market, as described above. Defendants accomplished this scheme by, *inter alia*, (i) fraudulently obtaining the '995 Enantiomer Patent, (ii) fraudulently listing the '995 Enantiomer Patent in the Orange Book, (iii) filing serial sham infringement litigation against multiple generic manufacturers claiming infringement of the fraudulently-obtained '995 Enantiomer Patent, (iv) filing a sham citizen petition, (v) fraudulently obtaining reissuance of the '995 Patent, (vi) unlawfully agreeing to divide a market and delay price reductions and generic competition for Lipitor, and (vii) otherwise conspiring to unlawfully monopolize and conspire to monopolize the market for atorvastatin calcium.

446. The goal, purpose and effect of Defendants' scheme was to prevent and delay the sale of atorvastatin calcium products in the United States at prices significantly below Pfizer's prices for Lipitor, thereby effectively preventing the average market price of atorvastatin calcium products from declining dramatically.

447. The goal, purpose, and effect of Defendants' scheme was also to maintain and extend Pfizer's monopoly power with respect to atorvastatin calcium products. Defendants' illegal scheme allowed Pfizer to continue charging supracompetitive prices for atorvastatin

calcium products, without a substantial loss of sales, reaping substantial unlawful monopoly profits. Defendants' scheme allowed Ranbaxy to reap the benefits of reduced generic competition in the United States and premature access to foreign markets.

448. Plaintiffs and members of the Class purchased substantial amounts of Lipitor and/or AB-rated generic equivalents indirectly from Defendants and/or other manufacturers.

449. The agreements between Pfizer and Ranbaxy are overt acts between separate economic entities—actual and potential competitors—and are illegal *per se* under state antitrust laws. Alternatively, this Complaint alleges that the agreements and conspiracy to monopolize are a violation of state antitrust law under a "quick look" or "rule of reason" analysis.

450. Defendants knowingly and intentionally engaged in sham litigation involving claims regarding the Process Patents (which had been rejected by a Delaware district court in earlier litigation) that Defendants knew, or should have known, were objectively baseless, in order to provide cover for an anticompetitive "settlement" agreement that extended the atorvastatin calcium monopoly and provided for global market allocation.

451. Defendants knew at the time Pfizer filed the second sham lawsuit that Pfizer had no realistic likelihood of success; therefore, Defendants knew that no reasonable pharmaceutical manufacturer in Pfizer's position would have believed it had a reasonable chance of succeeding on the merits. Ranbaxy knew, or should have known, that it was at no risk in the second litigation.

452. As a result of Defendants' illegal conduct, Plaintiffs and members of the Class were compelled to pay, and did pay, more than they would have paid for their atorvastatin calcium requirements absent Defendants' illegal conduct. But for Defendants' illegal conduct,

competitors would have begun selling generic Lipitor sooner than they did, and prices for atorvastatin calcium products would have been lower, sooner.

453. Had manufacturers of generic atorvastatin calcium products entered the market and lawfully competed with Defendants in a timely fashion, Plaintiffs and other members of the Class would have substituted lower-priced generic atorvastatin calcium products for the higher-priced brand-name Lipitor for some or all of their atorvastatin calcium products requirements, and/or would have paid lower net prices on their remaining Lipitor and AB-rated bioequivalent purchases.

454. But for Defendants' illegal conduct, competitors would have begun marketing generic versions of Lipitor well before November 30, 2011, and they would have been able to market such versions more successfully.

455. By engaging in the foregoing conduct, Defendants violated the following state antitrust laws:

a. Defendants intentionally and wrongfully engaged in a conspiracy to monopolize the relevant market in violation of Arizona Rev. Stat. §§ 44-1402, *et seq.*, with respect to purchases of Lipitor and AB-rated bioequivalents in Arizona by members of the Class.

b. Defendants intentionally and wrongfully engaged in a conspiracy to monopolize the relevant market in violation of Cal. Bus. & Prof. Code §§ 16700, *et seq.*, with respect to purchases of Lipitor and AB-rated bioequivalents in California by members of the Class.

c. Defendants intentionally and wrongfully engaged in a conspiracy to monopolize the relevant market in violation of D.C. Code §§ 28-4503, *et seq.*, with respect to

purchases of Lipitor and AB-rated bioequivalents in the District of Columbia by members of the Class.

d. Defendants intentionally and wrongfully engaged in a conspiracy to monopolize the relevant market in violation of Fla. Stat. §§ 501.201, *et seq.*, with respect to purchases of Lipitor and AB-rated bioequivalents in Florida by members of the Class, and this conduct constitutes a predicate act under the Florida Deceptive Practices Act.

e. Defendants intentionally and wrongfully engaged in a conspiracy to monopolize the relevant market in violation of Kan. Stat. Ann. §§ 50-101, *et seq.*, with respect to purchases of Lipitor and AB-rated bioequivalents in Kansas by members of the Class.

f. Defendants intentionally and wrongfully engaged in a conspiracy to monopolize the relevant market in violation of Me. Rev. Stat. Ann. 10, §§ 1102, *et seq.*, with respect to purchases of Lipitor and AB-rated bioequivalents in Maine by members of the Class.

g. Defendants intentionally and wrongfully engaged in a conspiracy to monopolize the relevant market in violation of Mass. Ann. Laws ch. 93A, *et seq.*, with respect to purchases of Lipitor and AB-rated bioequivalents in Massachusetts by members of the Class.

h. Defendants intentionally and wrongfully engaged in a conspiracy to monopolize the relevant market in violation of Mich. Comp. Laws Ann. §§ 445.772, *et seq.*, with respect to purchases of Lipitor and AB-rated bioequivalents in Michigan by members of the Class.

i. Defendants intentionally and wrongfully engaged in a conspiracy to monopolize the relevant market in violation of Minn. Stat. §§ 325D.49, *et seq.*, and Minn. Stat. § 8.31, *et seq.*, with respect to purchases of Lipitor and AB-rated bioequivalents in Minnesota by members of the Class.

j. Defendants intentionally and wrongfully engaged in a conspiracy to monopolize the relevant market in violation of Miss. Code Ann. §§ 75-21-3, *et seq.*, with respect to purchases of Lipitor and AB-rated bioequivalents in Mississippi by members of the Class.

k. Defendants intentionally and wrongfully engaged in a conspiracy to monopolize the relevant market in violation of Neb. Code Ann. §§ 59-802, *et seq.*, with respect to purchases of Lipitor and AB-rated bioequivalents in Nebraska by members of the Class.

l. Defendants intentionally and wrongfully engaged in a conspiracy to monopolize the relevant market in violation of Nev. Rev. Stat. Ann. §§ 598A.060, *et seq.*, with respect to purchases of Lipitor and AB-rated bioequivalents in Nevada by members of the Class.

m. Defendants intentionally and wrongfully engaged in a conspiracy to monopolize the relevant market in violation of N.M. Stat. Ann. §§ 57-1-2, *et seq.*, with respect to purchases of Lipitor and AB-rated bioequivalents in New Mexico by members of the Class.

n. Defendants intentionally and wrongfully engaged in a conspiracy to monopolize the relevant market in violation of New York General Business Law §§ 340, *et*

seq., with respect to purchases of Lipitor and AB-rated bioequivalents in New York by members of the Class.

o. Defendants intentionally and wrongfully engaged in a conspiracy to monopolize the relevant market in violation of N.C. Gen. Stat. §§ 75-2.1, *et seq.*, with respect to purchases of Lipitor and AB-rated bioequivalents in North Carolina by members of the Class.

p. Defendants intentionally and wrongfully engaged in a conspiracy to monopolize the relevant market in violation of N.D. Cent. Code §§ 51-08.1-02, *et seq.*, with respect to purchases of Lipitor and AB-rated bioequivalents in North Dakota by members of the Class.

q. Defendants intentionally and wrongfully engaged in a conspiracy to monopolize the relevant market in violation of 10 L.P.R.A. § 251, *et seq.*, with respect to purchases of Lipitor and AB-rated bioequivalents in Puerto Rico by members of the Class.

r. Defendants intentionally and wrongfully engaged in a conspiracy to monopolize the relevant market in violation of S.D. Codified Laws Ann. §§ 37-1-3.2, *et seq.*, with respect to purchases of Lipitor and AB-rated bioequivalents in South Dakota by members of the Class.

s. Defendants intentionally and wrongfully engaged in a conspiracy to monopolize the relevant market in violation of Tenn. Code Ann. §§ 47-25-101, *et seq.*, with respect to purchases of Lipitor and AB-rated bioequivalents in Tennessee by members of the Class.

t. Defendants intentionally and wrongfully engaged in a conspiracy to monopolize the relevant market in violation of Vt. Stat. Ann. 9, §§ 2453, *et seq.*, with respect to purchases of Lipitor and AB-rated bioequivalents in Vermont by members of the Class.

u. Defendants intentionally and wrongfully engaged in a conspiracy to monopolize the relevant markets in violation of W.Va. Code §§ 47-18-3, *et seq.*, with respect to purchases of Lipitor and AB-rated bioequivalents in West Virginia by members of the Class.

v. Defendants intentionally and wrongfully engaged in a conspiracy to monopolize the relevant market in violation of Wis. Stat. §§ 133.03, *et seq.*, with respect to purchases of Lipitor and AB-rated bioequivalents in Wisconsin by members of the Class.

456. Plaintiffs and members of the Class have been injured in their business or property by reason of Defendants' antitrust violations alleged in this Claim. Their injuries consist of: (1) being denied the opportunity to purchase lower-priced generic atorvastatin calcium products, sooner, and (2) paying higher prices for atorvastatin calcium products than they would have paid in the absence of Defendants' conduct. These injuries are of the type the antitrust laws were designed to prevent, and flow from that which makes Defendants' conduct unlawful.

457. Plaintiffs and the Class seek damages and multiple damages as permitted by law for their injuries by Defendants' violations of the aforementioned statutes.

THIRD CLAIM FOR RELIEF
For Conspiracy and Combination in Restraint of Trade Under State Law
(Asserted Against All Defendants)

458. Plaintiffs incorporate by reference the preceding allegations.

459. Defendants willfully and unlawfully engaged in a continuing illegal contract, combination, and conspiracy to restrain trade in the atorvastatin calcium market by engaging in an anticompetitive scheme to keep generic equivalents from the market and to allocate the market between horizontal competitors.

460. Defendants accomplished this scheme by, *inter alia*, (i) obtaining by actual fraud the '995 Enantiomer Patent, (ii) fraudulently listing the '995 Enantiomer Patent in the Orange Book, (iii) filing infringement litigation against multiple generic manufacturers claiming infringement of the fraudulently-obtained '995 Enantiomer Patent, (iv) filing a sham citizen petition, (v) fraudulently obtaining reissuance of the '995 Patent, (vi) unlawfully agreeing to divide the market and delay price reductions and generic competition for Lipitor in the United States, and (vii) entering into anticompetitive sham litigation and anticompetitive sham litigation settlements to cover the terms of the agreement allocating the market for atorvastatin calcium in the United States.

461. The goal, purpose, and effect of Defendants' scheme was to prevent and delay the sale of atorvastatin calcium products in the United States at prices significantly below Pfizer's prices for Lipitor, thereby effectively preventing the average market price of atorvastatin calcium products from declining dramatically. This effectively fixed the price of atorvastatin calcium products.

462. The goal, purpose and effect of Defendants' scheme was also to maintain and extend Pfizer's monopoly power with respect to atorvastatin calcium products. Defendants'

illegal scheme allowed Pfizer to continue charging supracompetitive prices for atorvastatin calcium products, without a substantial loss of sales, reaping substantial unlawful monopoly profits. Defendants' illegal scheme allowed Ranbaxy to reap the benefits of reduced generic competition in the United States and premature access to foreign markets.

463. Plaintiffs and members of the Class purchased substantial amounts of Lipitor and/or AB-rated generic equivalents indirectly from Defendants and/or other manufacturers.

464. The agreements between Defendants are horizontal market allocation and price fixing agreements between actual or potential competitors and are illegal *per se* under state antitrust laws. Alternatively, this Complaint alleges that these agreements are an unreasonable restraint of trade, in violation of state antitrust law, under a "quick look" or "rule of reason" analysis.

465. Defendants knowingly and intentionally engaged in sham litigation regarding process patent claims (that had been rejected by a Delaware district court in earlier litigation) that Defendants knew, or should have known, were objectively baseless in order to provide cover for an anticompetitive "settlement" agreement, outside the scope of the relevant patents, which divided the relevant market between horizontal competitors.

466. Alternatively, Pfizer's agreements, including its agreement with Ranbaxy, are presumptively anticompetitive reverse payment settlements, subject to "quick look" rule of reason scrutiny, because Pfizer provided substantial consideration in exchange for each generic manufacturer's agreement to delay market entrance.

467. Defendants knew at the time Pfizer filed this sham suit that Pfizer had no realistic likelihood of success; therefore, Defendants knew that no reasonable pharmaceutical manufacturer in Pfizer's position would have believed it had a reasonable chance of succeeding

on the merits. Ranbaxy knew, or should have known, that it was at no risk in the second litigation.

468. As a result of Defendants' illegal conspiracy and combination in restraint of trade, Plaintiffs and members of the Class were compelled to pay, and did pay, more than they would have paid for their atorvastatin calcium requirements absent Defendants' illegal conduct. But for Defendants' illegal conduct, competitors would have begun selling generic Lipitor sooner than they did, and prices for atorvastatin calcium products would have been lower, sooner.

469. Had other manufacturers of generic atorvastatin calcium products entered the market and lawfully competed with Defendants in a timely fashion, Plaintiffs and members of the Class would have substituted lower-priced generic atorvastatin calcium products for the higher-priced brand-name Lipitor for some or all of their atorvastatin calcium products requirements, and/or would have paid lower net prices on their remaining Lipitor and/or AB-rated bioequivalent purchases.

470. But for Defendants' illegal conduct, competitors would have begun marketing generic versions of Lipitor well before November 30, 2011, and would have been able to market such versions more successfully.

471. By engaging in the foregoing conduct, Defendants violated the following state antitrust laws:

a. Defendants intentionally and wrongfully engaged in a combination and conspiracy in restraint of trade in violation of Arizona Rev. Stat. §§ 44-1402, *et seq.*, with respect to purchases of Lipitor and AB-rated bioequivalents in Arizona by members of the Class.

b. Defendants intentionally and wrongfully engaged in a combination and conspiracy in restraint of trade in violation of Cal. Bus. & Prof. Code §§ 16700, *et seq.*, with respect to purchases of Lipitor and AB-rated bioequivalents in California by members of the Class.

c. Defendants intentionally and wrongfully engaged in a combination and conspiracy in restraint of trade in violation of D.C. Code §§ 28-4502, *et seq.*, with respect to purchases of Lipitor and AB-rated bioequivalents in the District of Columbia by members of the Class.

d. Defendants intentionally and wrongfully engaged in a combination and conspiracy in restraint of trade in violation of Fla. Stat. §§ 501.201, *et seq.*, with respect to purchases of Lipitor and AB-rated bioequivalents in Florida by members of the Class.

e. Defendants intentionally and wrongfully engaged in a combination and conspiracy in restraint of trade in violation of Kan. Stat. Ann. §§ 50-101, *et seq.*, with respect to purchases of Lipitor and AB-rated bioequivalents in Kansas by members of the Class.

f. Defendants intentionally and wrongfully engaged in a combination and conspiracy in restraint of trade in violation of Me. Rev. Stat. Ann. 10, §§ 1101, *et seq.*, with respect to purchases of Lipitor and AB-rated bioequivalents in Maine by members of the Class.

g. Defendants intentionally and wrongfully engaged in a combination and conspiracy in restraint of trade in violation of Mass. Ann. Laws ch. 93A, *et seq.*,

with respect to purchases of Lipitor and AB-rated bioequivalents in Massachusetts by members of the Class.

h. Defendants intentionally and wrongfully engaged in a combination and conspiracy in restraint of trade in violation of Mich. Comp. Laws Ann. §§ 445.772, *et seq.*, with respect to purchases of Lipitor and AB-rated bioequivalents in Michigan by members of the Class.

i. Defendants intentionally and wrongfully engaged in a combination and conspiracy in restraint of trade in violation of Minn. Stat. §§ 325D.49, *et seq.*, with respect to purchases of Lipitor and AB-rated bioequivalents in Minnesota by members of the Class.

j. Defendants intentionally and wrongfully engaged in a combination and conspiracy in restraint of trade in violation of Miss. Code Ann. §§ 75-21-3, *et seq.*, with respect to purchases of Lipitor and AB-rated bioequivalents in Mississippi by members of the Class.

k. Defendants intentionally and wrongfully engaged in a combination and conspiracy in restraint of trade in violation of Neb. Code Ann. §§ 59-801, *et seq.*, with respect to purchases of Lipitor and AB-rated bioequivalents in Nebraska by members of the Class.

l. Defendants intentionally and wrongfully engaged in a combination and conspiracy in restraint of trade in violation of Nev. Rev. Stat. Ann. §§ 598A.060, *et seq.*, with respect to purchases of Lipitor and AB-rated bioequivalents in Nevada by members of the Class.

m. Defendants intentionally and wrongfully engaged in a combination and conspiracy in restraint of trade in violation of N.M. Stat. Ann. §§ 57-1-1, *et seq.*, with respect to purchases of Lipitor and AB-rated bioequivalents in New Mexico by members of the Class.

n. Defendants intentionally and wrongfully engaged in a combination and conspiracy in restraint of trade in violation of New York General Business Law §§ 340, *et seq.*, with respect to purchases of Lipitor and AB-rated bioequivalents in New York by members of the Class.

o. Defendants intentionally and wrongfully engaged in a combination and conspiracy in restraint of trade in violation of N.C. Gen. Stat. §§ 75-1, *et seq.*, with respect to purchases of Lipitor and AB-rated bioequivalents in North Carolina by members of the Class.

p. Defendants intentionally and wrongfully engaged in a combination and conspiracy in restraint of trade in violation of N.D. Cent. Code §§ 51-08.1-02, *et seq.*, with respect to purchases of Lipitor and AB-rated bioequivalents in North Dakota by members of the Class.

q. Defendants intentionally and wrongfully engaged in a combination and conspiracy in restraint of trade in violation of 10 L.P.R.A. § 251, *et seq.*, with respect to purchases of Lipitor and AB-rated bioequivalents in Puerto Rico by members of the Class.

r. Defendants intentionally and wrongfully engaged in a combination and conspiracy in restraint of trade in violation of S.D. Codified Laws Ann. §§ 37-1-

3.1, *et seq.*, with respect to purchases of Lipitor and AB-rated bioequivalents in South Dakota by members of the Class.

s. Defendants intentionally and wrongfully engaged in a combination and conspiracy in restraint of trade in violation of Tenn. Code Ann. §§ 47-25-101, *et seq.*, with respect to purchases of Lipitor and AB-rated bioequivalents in Tennessee by members of the Class.

t. Defendants intentionally and wrongfully engaged in a combination and conspiracy in restraint of trade in violation of Vt. Stat. Ann. 9, §§ 2453, *et seq.*, with respect to purchases of Lipitor and AB-rated bioequivalents in Vermont by members of the Class.

u. Defendants intentionally and wrongfully engaged in a combination and conspiracy in restraint of trades in violation of W.Va. Code §§ 47-18-3, *et seq.*, with respect to purchases of Lipitor and AB-rated bioequivalents in West Virginia by members of the Class.

v. Defendants intentionally and wrongfully engaged in a combination and conspiracy in restraint of trade in violation of Wis. Stat. §§ 133.03, *et seq.*, with respect to purchases of Lipitor and AB-rated bioequivalents in Wisconsin by members of the Class.

472. Plaintiffs and members of the Class have been injured in their business or property by reason of Defendants' antitrust violations alleged in this Claim. Their injuries consist of: (1) being denied the opportunity to purchase lower-priced generic atorvastatin calcium products, sooner, and (2) paying higher prices for atorvastatin calcium products than they would have paid in the absence of Defendants' conduct. These injuries are of the type the

antitrust laws were designed to prevent, and flow from that which makes Defendants' conduct unlawful.

473. Plaintiffs and the Class seek damages and multiple damages as permitted by law for their injuries by Defendants' violations of the aforementioned statutes.

FOURTH CLAIM FOR RELIEF
For Unfair And Deceptive Trade Practices Under State Law
(Asserted Against All Defendants)

474. Plaintiffs incorporate by reference the preceding allegations and paragraphs.

475. Defendants engaged in unfair competition or unfair, unconscionable, deceptive, or fraudulent acts or practices in violation of the state consumer protection statutes listed below. As a direct and proximate result of Defendants' anticompetitive, deceptive, unfair, unconscionable, and fraudulent conduct, Plaintiffs and Class members were deprived of the opportunity to purchase a generic version of Lipitor and forced to pay higher prices for their atorvastatin requirements.

476. There was a gross disparity between the price that Plaintiffs and the Class members paid for the brand product and the value received, given that a much cheaper substitute generic product should have been available.

477. By engaging in the foregoing conduct, Defendants violated the following state unfair and deceptive trade practices and consumer fraud laws:

a. Defendants engaged in unfair competition or unfair or deceptive acts or practices in violation of Ark. Code § 4-88-101, *et seq.*, with respect to purchases of Lipitor and AB-rated bioequivalents in Arkansas by members of the Class.

b. Defendants engaged in unfair competition or unfair or deceptive acts or practices in violation of Cal. Bus. & Prof. Code §§ 17200, *et seq.*, with respect to purchases of Lipitor and AB-rated bioequivalents in California by members of the Class.

c. Defendants engaged in unfair competition or unfair or deceptive acts or practices in violation of D.C. Code § 28-3901, *et seq.*, with respect to purchases of Lipitor and AB-rated bioequivalents in the District of Columbia by members of the Class.

d. Defendants engaged in unfair competition or unfair or deceptive acts or practices in violation of Fla. Stat. § 501.201, *et seq.*, with respect to purchases of Lipitor and AB-rated bioequivalents in Florida by members of the Class.

e. Defendants engaged in unfair competition or unfair or deceptive acts or practices in violation of Idaho Code § 48-601, *et seq.*, with respect to purchases of Lipitor and AB-rated bioequivalents in Idaho by members of the Class.

f. Defendants engaged in unfair competition or unfair or deceptive acts or practices in violation of 5 Me. Rev. Stat. § 207, *et seq.*, with respect to purchases of Lipitor and AB-rated bioequivalents in Maine by members of the Class.

g. Defendants engaged in unfair competition or unfair or deceptive acts or practices in violation of Mass. Ann. Laws ch. 93A, *et seq.*, with respect to purchases of Lipitor and AB-rated bioequivalents in Massachusetts by members of the Class

h. Defendants engaged in unfair competition or unfair or deceptive acts or practices in violation of Minn. Stat. § 325F.68, *et seq.*, and Minn. Stat. § 8.31, *et seq.*, with respect to purchases of Lipitor and AB-rated bioequivalents in Minnesota by members of the Class.

i. Defendants engaged in unfair competition or unfair or deceptive acts or practices in violation of Missouri Stat. § 407.010, *et seq.*, with respect to purchases of Lipitor and AB-rated bioequivalents in Missouri by members of the Class.

j. Defendants engaged in unfair competition or unfair or deceptive acts or practices in violation of Neb. Rev. Stat. § 59-1601, *et seq.*, with respect to purchases of Lipitor and AB-rated bioequivalents in Nebraska by members of the Class.

k. Defendants engaged in unfair competition or unfair or deceptive acts or practices in violation of N.H. Rev. Stat. § 358-A: 1, *et seq.*, with respect to purchases of Lipitor and AB-rated bioequivalents in New Hampshire by members of the Class.

l. Defendants engaged in unfair competition or unfair or deceptive acts or practices in violation of N.M. Stat. § 57-12-1, *et seq.*, with respect to purchases of Lipitor and AB-rated bioequivalents in New Mexico by members of the Class.

m. Defendants engaged in deceptive acts or practices in violation of New York General Business Law §§ 349, *et seq.*, with respect to purchases of Lipitor and AB-rated bioequivalents in New York by members of the Class.

n. Defendants engaged in unfair competition or unfair or deceptive acts or practices in violation of 73 Pa. Stat. Ann. §§ 201-1, *et seq.*, with respect to purchases of Lipitor and AB-rated bioequivalents in Pennsylvania by members of the Class.

o. Defendants engaged in unfair competition or unfair or deceptive acts or practices in violation of Vt. Stat. Ann. 9, § 2453, *et seq.*, with respect to purchases of Lipitor and AB-rated bioequivalents in Vermont by members of the Class.

p. Defendants engaged in unfair competition or unfair or deceptive acts or practices in violation of Va. Code Ann. § 59.1-196, *et seq.*, with respect to purchases of Lipitor and AB-rated bioequivalents in Virginia by members of the Class.

478. Plaintiffs and members of the Class have been injured in their business and property by reason of Defendants' anticompetitive, unfair or deceptive acts alleged in this Claim. Their injury consists of paying higher prices for Lipitor and/or its AB-rated bioequivalents than they would have paid in the absence of these violations. This injury is of the type the state consumer protection statutes were designed to prevent and directly results from Defendants' unlawful conduct.

FIFTH CLAIM FOR RELIEF
Unjust Enrichment
(Asserted Against All Defendants)

479. Plaintiffs incorporate by reference the preceding allegations.

480. Defendants have benefited from the monopoly profits on their sales of Lipitor and/or AB-rated bioequivalents resulting from the unlawful and inequitable acts alleged in this Complaint.

481. Defendants' financial benefits resulting from their unlawful and inequitable conduct are traceable to overpayments for Lipitor and AB-rated bioequivalents by Plaintiffs and members of the Class.

482. Plaintiffs and the Class have conferred upon Defendants an economic benefit, in the nature of profits resulting from unlawful overcharges and monopoly profits, to the economic detriment of Plaintiffs and the Class.

483. It would be futile for Plaintiffs and the Class to seek a remedy from any party with whom they had privity of contract. Defendants have paid no consideration to anyone for any benefits received indirectly from Plaintiffs and the Class.

484. It would be futile for Plaintiffs and the Class to seek to exhaust any remedy against the immediate intermediary in the chain of distribution from which it indirectly purchased Lipitor or its generic equivalents, as they are not liable and would not compensate Plaintiffs for unlawful conduct caused by Defendants.

485. The economic benefit of overcharges and unlawful monopoly profits derived by Defendants through charging supracompetitive and artificially inflated prices for Lipitor and/or its generic equivalents is a direct and proximate result of Defendants' unlawful practices.

486. The financial benefits derived by Defendants rightfully belongs to Plaintiffs and the Class, as Plaintiffs and the Class paid anticompetitive and monopolistic prices during the Class Period, inuring to the benefit of Defendants.

487. It would be inequitable under unjust enrichment principles in the District of Columbia and all of the fifty states, except for Ohio and Indiana, for the Defendants to be permitted to retain any of the overcharges for Lipitor and/or its AB-rated bioequivalents derived from Defendants' unfair and unconscionable methods, acts and trade practices alleged in this Complaint.

488. Defendants are aware of and appreciate the benefits bestowed upon them by Plaintiffs.

489. Defendants should be compelled to disgorge in a common fund for the benefit of Plaintiff and the Class all unlawful or inequitable proceeds received by them.

490. A constructive trust should be imposed upon all unlawful or inequitable sums received by Defendants traceable to Plaintiffs and the Class.

491. Plaintiffs and the Class have no adequate remedy at law.

XIII. DEMAND FOR JUDGMENT

WHEREFORE, Plaintiffs, on behalf of themselves and the End-Payor Class, demand judgment for the following relief:

A. Determine that this action may be maintained as a class action pursuant to Fed. R. Civ. P. 23(a) and (b)(3), and direct that reasonable notice of this action, as provided by Fed. R. Civ. P. 23(c)(2), be given to the Class and declare the Plaintiffs representative of the End-Payor Class;

B. Declare that the conduct alleged herein is in violation of the statutes set forth above, and of the common law of unjust enrichment in the District of Columbia and all of the fifty states except for Ohio and Indiana;

C. Enter joint and several judgments against Defendants in favor of Plaintiffs and the End-Payor Class;

D. Grant Plaintiffs and the Class equitable relief in the nature of disgorgement, restitution, and the creation of a construction trust to remedy Defendants' unjust enrichment;

E. Award the End-Payor Class damages and, where applicable, treble, multiple, punitive, and/or other damages, in an amount to be determined at trial, including interest;

F. Award Plaintiffs and the End-Payor Class their costs of suit, including reasonable attorneys' fees and experts' fees as provided by law; and

G. Grant such other further relief as is necessary to correct for the anticompetitive market effects caused by the unlawful conduct of Defendants, and as the Court deems just.

XIV. JURY DEMAND

Pursuant to Fed. Civ. P. 38, Plaintiffs on behalf of themselves and the proposed class demand a trial by jury on all issues so triable.

Dated: September 10, 2012

Respectfully submitted,

s/ Lisa J. Rodriguez
Lisa J. Rodriguez
Trujillo Rodriguez & Richards, LLC
258 Kings Highway East
Haddonfield, NJ 08033
Tel: (856) 795-9002
Fax: (856) 795-9887
lisa@trrlaw.com

Interim Liaison Counsel for the Proposed End-Payor Class

Interim Co-Lead Counsel for the Proposed End-Payor Class

Michael M. Buchman
Adam G. Kurtz
Pomerantz Haudek Grossman & Gross LLP
100 Park Avenue, 26th Floor
New York, New York 10017
Telephone: (212) 661-1100
Fax: (212) 661-8665
mbuchman@pomlaw.com
agkurtz@pomlaw.com

Vincent J. Esades
David Woodward
Renae D. Steiner
James W. Anderson
Heins Mills & Olson, P.L.C.
310 Clifton Avenue
Minneapolis, MN 55403
Telephone: (612) 338-4605
Fax: (612) 338-4692
vesades@heinsmills.com
dwoodward@heinsmills.com
rsteiner@heinsmills.com
janderson@heinsmills.com

J. Douglas Richards
Sharon K. Robertson
Cohen Milstein Sellers & Toll, PLLC
88 Pine Street, 14th Floor
New York, New York 10005
Telephone: (212) 838-7797
Fax: (212) 838-7745
drichards@cohenmilstein.com
srobertson@cohenmilstein.com

Kenneth A. Wexler
Bethany R. Turke
Justin N. Boley
Wexler Wallace LLP
55 W. Monroe Street, Suite 3300
Chicago, IL 60603
Telephone: (312) 346-2222
Fax: (312) 346-0022
kaw@wexlerwallace.com
brt@wexlerwallace.com
jnb@wexlerwallace.com

Executive Committee for the Proposed End-Payor Class

James G. Stranch, III
J. Gerard Stranch IV
Joe P. Leniski
Branstetter Stranch & Jennings PLLC
227 Second Avenue North, 4th Floor
Nashville, TN 37201-1631
Telephone: (615) 254-8801
Fax: (615) 255-5419
jims@branstetterlaw.com
gerards@branstetterlaw.com
joeyl@branstetterlaw.com

Jayne A. Goldstein
Shepherd, Finkelman, Miller & Shah, LLP
1640 Tower Center Circle, Suite 216
Weston, FL 33326
Telephone: (954) 515-0123
jgoldstein@sfmslaw.com

Natalie Finkelman Bennett
James C. Shah
Shepherd, Finkelman, Miller & Shah, LLP
475 White Horse Pike
Collingswood, NJ 08107
Telephone: (856) 858-1770
nfinkelman@sfmslaw.com
jshah@sfmslaw.com

Douglas R. Plymale
David Franco
Kevin Oufnac
James R. Dugan, II
Dugan Law Firm, PLC
One Canal Place
365 Canal Street, Suite 1000
New Orleans, LA 70130
Telephone: (504) 648-0180
Fax: (504) 648-0181
jdugan@dugan-lawfirm.com

Lawrence G. Papale
Law Office of Lawrence G. Papale
1308 Main Street, Suite 117
St. Helena, CA 94574
Telephone: (707): 963-1704
Fax: (707) 963-0706
lgpaple@papalelaw.com

Joseph G. Sauder
Benjamin F. Johns
Matthew David Schelkopf
Chimicles & Tikellis LLP
One Haverford Centre
361 West Lancaster Avenue
Haverford, PA 19041
Telephone: (610) 642-8500
jgs@chimicles.com
bfj@chimicles.com
mds@chimicles.com

Judy Scolnick
Scott + Scott LLP
500 5th Avenue, 40th Floor
New York, NY 10110
Telephone: (212) 223-6444
Fax: (212) 223-6334
jscolnick@scott-scott.com

Counsel for the Proposed End-Payor Class

Glen DeValerio
Nathaniel L. Orenstein
Berman DeValerio
One Liberty Square
Boston, MA 02109
Telephone: (617) 542-8300
Fax: (617) 542-1194
gdevalerio@bermandevalerio.com
norenstein@ bermandevalerio.com

Heidi M. Silton
Lockridge Grindal Nauen, P.L.L.P.
100 Washington Avenue South, Suite 2200
Minneapolis, MN 55401
Telephone: (612) 339-6900
Fax: (612) 339-0981
hmsilton@locklaw.com

Todd A. Seaver
Berman DeValerio
One California Street, Suite 900
San Francisco, CA 94111
Telephone: (415) 433-3200
Fax: (415) 433-6382
tseaver@bermandevalerio.com

Shane Youtz
Youtz & Valdez, P.C.
900 Gold Avenue S.W.
Albuquerque, New Mexico 87102
Telephone: (505) 244-1200
Fax: (505) 244-9700

Art Sadin
Sadin Law Firm, P.C.
121 E. Magnolia Street
Suite 102
Friendswood, Texas 77546
Telephone: (281) 648-7711
Fax: (281) 648-7799

Jeffrey L. Kodroff
John Macoretta
Spector, Roseman, Kodroff & Willis, P.C.
1818 Market Street, Suite 2500
Philadelphia, PA 19103
Telephone: (215) 496-0300
Fax: (215) 496-6611
jkodroff@srkw-law.com
j macoretta@srkw-law.com

Charles Crueger
Erin Dickinson
Thomas S. Reynolds II
Hansen Riederer Dickinson Crueger LLC
316 N. Milwaukee St., Suite 200
Milwaukee, WI 53202
Telephone: (414) 273-8474
Fax: (414) 273-8476
charles@hrdc-law.com
erin@hrdc-law.com
thomas@hrdc-law.com

Lee Albert
Benjamin Bianco
Gregory A. Frank
Murray Frank LLP
275 Madison Avenue, Suite 801
New York, New York 10016
Telephone: (212) 682-1818
Fax: (212) 682-1892
lalbert@murrayfrank.com
bbianco@murrayfrank.com
gfrank@murrayfrank.com

Arnold Levin
Fred S. Longer
Levin Fishbein Sedran & Berman
510 Walnut Street, Suite 500
Philadelphia, PA 19106
Telephone: (215) 592-1500
Fax: (215) 592-4663

Christopher A. Seeger
James A. O'Brien III
Christopher M. Van de Kieft
Seeger Weiss LLP
77 Water Street, 26th Floor
New York, NY 10005
Telephone: (212) 584-0700
Fax: (212) 584-0799

David Pastor
Pastor Law Office, LLP
63 Atlantic Avenue, 3rd Floor
Boston, MA 02110
Telephone: (617) 742-9700
Fax: (617) 742-9701
dpastor@gilmanpastor.com

Jonathan Shub
Seeger Weiss LLP
1515 Market Street
Philadelphia, PA 19102
Telephone: (215) 504-2300

James Cecchi
Carella, Byrne, Bain, Gilfillan,
Cecchi, Stewart & Olstein, P.C.
5 Becker Farm Rd.
Roseland, NJ 07068
Telephone: (973) 994-1700
Fax: (973) 994-1744
jcecchi@carellabyrne.com

John I. Alioto
Alioto & Alioto LLP
1127 Pope Street, Suite 201
St. Helena, CA 94574
Telephone: (707) 963-0606
Fax: (707) 963-5128

David M. Cialkowski
Anne T. Regan
Brian C. Gudmundson
Aditya Bharadwaj
Zimmerman Reed, PLLP
80 South Eighth Street
Minneapolis, MN 55402
Telephone: (612) 341-0400
Fax: (612) 341-0844
david.cialkowski@zimmreed.com
anne.regan@zimmreed.com
brian.gudmundson@zimmreed.com
adi.bharadwaj@zimmreed.com

Michael DeBenedictis
Debenedictis & Debenedictis LLC
125 Kings Highway West
Haddonfield, NJ 08033
Telephone: (856) 795 2101
mjd@debenedictislaw.com

Robert G. Methvin, Jr.
James M. Terrell
Nicholas W. Armstrong
McCallum, Methvin & Terrell, P.C.
2201 Arlington Avenue South
Birmingham, AL 35205
Telephone: (205) 939-3006
Fax: (205) 939-0399

Joel C. Meredith
Krishna B. Narine
Meredith & Narine
1521 Locust Street, 8th floor
Philadelphia, PA 19102
Telephone: (215) 564-5182
Fax: (215) 569-0958
knarine@m-npartners.com
jmeredith@m-npartners.com

Douglas A. Millen
Donald L. Sawyer
Freed Kanner London & Millen, LLC
2201 Waukegan Road, Suite 130
Bannockburn, IL 60015
Telephone: (224) 632-4509
Fax: (224) 632-4521
dmillen@fklmlaw.com
dsawyer@fklmlaw.com

Michael A. Rose
Frank R. Schirripa
Hach Rose Schirripa & Cheverie LLP
185 Madison Avenue, 14th Floor
New York, New York 10016
Telephone: (212) 213-8311
Fax: (212) 779-0028

Bryan L. Clobes
Ellen Meriwether
Cafferty Clobes Meriwether &
Sprengel LLP
1717 Arch St., Suite 3610
Philadelphia, PA 19103
Telephone: (215) 864-2800
Fax: (215) 864-2810
bclobes@caffertyclobes.com
emeriwether@caffertyclobes.com

Jonathan Shapiro
Stern Shapiro Weissberg & Garin
90 Canal Street
Boston, MA 02114
Telephone: (617) 742-5800
Fax: (617) 742-5858
jshapiro@sswg.com

Robert D. Klausner
Stuart A. Kaufman
Klausner Kaufman Jensen & Levinson
10059 Northwest 1st Court
Plantation, FL 33324
Telephone: (954) 916-1202
Fax: (954) 916-1232
bob@robertdklausner.com
stu@robertdklausner.com

Michael A. London
Virginia E. Anello
Douglas & London PC
111 John Street, 14th Floor
New York, NY 10038
Telephone**:** (212)566-7500
Fax: (212)566-7501

Robert G. Methvin
James M. Terrell
Nicholas W. Armstrong
McCallum Methvin & Terrell PC
2201 Arlington Avenue
South Birmingham, AL 35205
(205) 939-0199

Robert J Bonsignore
Richard Kirchner
Robin E Brewer
Bonsignore & Brewer
23 Forest St,
Medford, MA 02155
(781) 350-0000
rbonsignore@class-actions.us
rkirchner@class-actions.us
rbrewer@class-actions.us

G. Courtney French
Fuston, Petway & French LLP
600 Luckie Drive
Birmingham, AL 35223
(205) 977-9798
cfrench@fplaw.com

Paul Echohawk
Echohawk Law Offices
505 Pershing Avenue, P.O. Box 6119,
Pocatello, Idaho 83205
(208) 478.1624
paul@echohawk.com

Christopher Welsh
Welsh & Welsh PC
9290 West Dodge Road
Omaha, NE 68114
(402) 384-8160
cwelsh@welsh-law.com

Terry Gross
Adam C. Belsky
Sarah Crowley
Gross Belsky Alonso LLP
One Sansome Street, Suite 3670
San Francisco, CA 94104
Tel: 415 544-0200
Fax: 415 544-0201
terry@gba-law.com
adam@gba-law.com
sarah@gba-law.com

Gary Nitsche
Weik, Nitsche & Dougherty
305 North Union Street, Second Floor,
P.O. BOX 2324
Wilmington, DE 19899
(302) 856-9868
gnitsche@attys4u.com

J. Ryan Fowler
John D. Sloan Jr.
Sloan Bagley Hatcher & Perry
101 East Whaley Street
Longview, TX 75601
(903) 757-7000
rfowler@sloanfirm.com

Wayne Parsons
Wayne Parsons Law Office
1406 Colburn Street #201
Honolulu, HI 96817
(808) 845-2211
wparsons@hawaii.rr.com

Vincent Glorioso III
The Glorioso Law Firm
815 Baronne Street
New Orleans, LA 70113
(504) 569-9999
maria@gtorts.com

John Rausch
Rausch Law Firm
3909 University Avenue
Waterloo, IA 50701
(319) 233-3557
rauschlawfirm@dybb.com

Cindy Smith:
Jasper Smith Olson PC
202 West Spruce Street
Missoula, MT 59802
(406) 541-7177
cks@montanalaw.com

Alexa D'Amato
D'Amato Law Firm
2900 Fire Road Suite 200
Egg Harbor Township, NJ 08234
Office: 609.926.3300
Fax: 609.926.3883
Alexa@damatolawfirm.com

Samuel K. Rudman
Lambert Coffin
477 Congress St
Portland, ME 04101
(207) 874-4000
srudman@lambertcoffin.com

D. Mitchell Garrett Jr.
Garrett Law Center
215 State Street #304
Muskogee, OK 74401
(888) 655-2923
Mitchell@garrettlawcenter.com

Luis E. Minana
Luis E. Minana & Associates
122 Avenue D
San Juan, Puerto Rico 00918
(787) 758-1999
minanalaw@prtc.net

D. Michael Noonan:
Shaheen & Gordon
P.O. Box 977
Dover, NH 03821-0977
(603) 749-5000
mnoonan@shaheengordon.com

Stephen M. Smith
Brain Injury Law Center
2100 Kecoughtan Road
Hampton, VA 23661
(757) 357-2404
ssmith@braininjurylawcenter.com

R. Christopher Gilreath:
Gilreath & Associates
550 W Main St # 600
Knoxville, TN 37902
(865) 637-2442
chrisgil@sidgilreath.com

Michael D. Fitzgerald
Law Office of Michael D. Fitzgerald
800 Old Bridge Road
Brielle, NJ 08730
mdfitz@briellelaw.com

Troy Giatras
The Giatras Law Firm
118 Capitol Street #400
Charleston, WV 25301
(304) 343-2900
troy@thewvlawfirm.com

Andriana Contartese
242 West Broadway
Boston, MA 02127
adriana911@juno.com

Carl Beckwith
Carl Beckwith, Esq., PC
1 Closter Commons, #181
Closter, NJ 07624
201-338-2833
Fax: (201) 567-5222
ccbeckwith@gmail.com

Charles Andrew O'Brien , III
Charles Andrew O'Brien, Attorney at Law
5525 Reitz Ave.
P. O. Box 98029
Baton Rouge, LA 70898
225-295-2454
Andy.OBrien@bcbsla.com

Jeffrey Padwa, Esq.
444 Westminster Street, 2nd Floor
Providence, RI 02903
jpadwa@providenceri.com

Ira Neil Richards
Trujillo Rodriguez & Richards, LLC
1717 Arch Street, Suite 3838
Philadelphia, PA 19103
Telephone: (215) 731-9004
Fax: (215) 731-9044
ira@trrlaw.com

Brian M. Sund
Jackson D. Bigham
Morrison Sund PLLC
5125 County Road 101, Suite 202
Minnetonka, MN 55345
Tel.: (952) 975-0050
Fax: (952) 975-0058